

EXHIBIT D

Michael Karram, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,) Master File No.
PELVIC REPAIR SYSTEM) 2:12-MD-02327
PRODUCTS LIABILITY) MDL NO. 2327
LITIGATION) JOSEPH R. GOODWIN
) U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO:)
)
Donna Massey) Case No. 2:12-cv-00880
Thelma Wright) Case No. 2:12-cv-01090
Sharon Boggs) Case No. 2:12-cv-00368
Margaret Kirkpatrick) Case No. 2:12-cv-00746
Paula Kriz) Case No. 2:12-cv-00938
Miranda Patterson) Case No. 2:12-cv-00481

DEPOSITION OF MICHAEL KARRAM, M.D.

March 29, 2016
10:02 a.m.

Taken at:
Frost, Brown & Todd, LLC
301 East Fourth Street
3300 Great American Tower
Cincinnati, Ohio

Reported by: Carol A. Kirk, RPR, RMR

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Michael Karram, M.D.

Page 2	Page 4
<p>1 DEPOSITION OF MICHAEL KARRAM, M.D. 2 APPEARANCES 3 --- 4 JOSEPH J. ZONIES, ESQUIRE REILLY POZNER LLP 5 1900 Sixteenth Street, Suite 1700 Denver, Colorado 80202 6 303-893-6100 jzonies@rplaw.com, 7 8 and 9 JAMES W. LAMPKIN, III, ESQUIRE (VIA TELECONFERENCE) WESLEY CHADWICK COOK, ESQUIRE (VIA TELECONFERENCE) 10 BEASLEY, ALLEN, CROW, METHVIN, PORTIS & MILES, P.C. 218 Commerce Street Montgomery, Alabama 36104 11 334-269-2343 james.lampkin@beasleyallen.com 12 chad.cook@beasleyallen.com 13 On behalf of the Plaintiffs. 14 15 DOUGLAS J. DIPAOLO, M.D., ESQUIRE BUTLER SNOW LLP 1020 Highland Colony Parkway, Suite 1400 16 Ridgeland, Mississippi 39157 601-948-5711 17 douglas.dipaola@butlersnow.com, 18 On behalf of the Defendants. 19 20 ALSO PRESENT: 21 Shea Shaver, Reilly Pozner 22 23 --- 24</p>	<p>1 DEPOSITION OF MICHAEL KARRAM, M.D. 2 INDEX TO EXHIBITS 3 EXHIBIT DESCRIPTION PAGE 4 1 NOTICE TO TAKE DEPOSITION OF 7 DR. MICHAEL KARRAM 5 6 2 GENERAL TVT REPORT PREPARED BY 7 MICHAEL KARRAM, M.D. 7 3 CURRICULUM VITAE OF MICHAEL 7 KARRAM, M.D. 8 9 4 DOCUMENT ENTITLED, "RELIANCE 7 LIST, IN ADDITION TO MATERIALS 10 REFERENCED IN REPORT, MDL 11 WAVE 1" 12 5 CURRICULUM VITAE OF MICHAEL 9 KARRAM, M.D. 13 14 6 GENERAL TVT REPORT PREPARED BY 10 MICHAEL KARRAM, M.D. 15 7 FEDERAL REGISTER, VOLUME 70, 67 NO. 147, TUESDAY, AUGUST 2, 2005, NOTICES, PAGES 44376-44387 16 17 8 ARTICLE ENTITLED, "RETROPUBIC 96 VERSUS TRANSOBTURATOR 18 MIDURETHRAL SLINGS FOR STRESS 19 INCONTINENCE" 20 9 ARTICLE ENTITLED, "TENSION-FREE 108 VAGINAL TAPE (TVT) IN WOMEN 21 WITH RECURRENT STRESS URINARY 22 INCONTINENCE - A LONG-TERM 23 FOLLOW UP" 24 10 ARTICLE ENTITLED, "A THREE-YEAR 110 FOLLOW UP OF TENSION FREE VAGINAL TAPE FOR SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE"</p>
Page 3	Page 5
<p>1 Tuesday Morning Session March 29, 2016 2 10:02 a.m. 3 --- 4 STIPULATIONS 5 It is stipulated by and among counsel for the 6 respective parties that the deposition of MICHAEL 7 KARRAM, M.D., a Witness herein, called by the Plaintiffs 8 under the applicable Federal Rules of Civil Procedure, 9 may be taken at this time in stenotype by the Notary, 10 pursuant to notice; that said deposition may thereafter 11 be transcribed by the Notary out of the presence of the 12 witness; that proof of the official character and 13 qualification of the Notary is waived; that the witness 14 may sign the transcript of his deposition before a 15 Notary other than the Notary taking his deposition; said 16 deposition to have the same force and effect as though 17 signed before the Notary taking it. 18 --- 19 20 21 22 23 24</p>	<p>1 INDEX TO EXHIBITS (CONT'D) 2 EXHIBIT DESCRIPTION PAGE 3 11 INVITATION FOR ADVANCED PELVIC 128 FLOOR COURSE, COURSE 2, BATES- 4 STAMPED ETH.MESH.00789838 5 12 INVITATION FOR ADVANCED PELVIC 130 FLOOR COURSE, BATES-STAMPED 6 ETH.MESH.01678144 7 13 SPREADSHEET BATES-STAMPED 132 ETH.MESH.04181701 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

Michael Karram, M.D.

Page 6	Page 8
<p>1 INDEX TO EXAMINATION</p> <p>2 WITNESS PAGE</p> <p>3 MICHAEL KARRAM, M.D.</p> <p>4 EXAMINATION BY MR. ZONIES: 7</p> <p>5 EXAMINATION BY MR. DIPAOLO: 140</p> <p>6 FURTHER EXAMINATION BY MR. ZONIES: 143</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 BY MR. ZONIES:</p> <p>2 Q. Good morning, sir. Could you please state</p> <p>3 your name for the record.</p> <p>4 A. Michael Karram.</p> <p>5 Q. And you are a medical doctor?</p> <p>6 A. Yes, I am.</p> <p>7 Q. What is your specialty?</p> <p>8 A. Gynecology and urogynecology.</p> <p>9 Q. How long have you been practicing medicine?</p> <p>10 A. Since 1984.</p> <p>11 Q. Sir, my name is Joe Zonies. I represent the</p> <p>12 Plaintiffs in this matter.</p> <p>13 Do you understand what your role is here</p> <p>14 today?</p> <p>15 A. Yes, I do.</p> <p>16 Q. What is it?</p> <p>17 A. To testify on a report that I prepared on a</p> <p>18 procedure used for stress urinary incontinence.</p> <p>19 Q. On whose behalf are you testifying?</p> <p>20 A. On behalf of the defense.</p> <p>21 Q. And who is that?</p> <p>22 A. Would be Ethicon Endo-Surgery or J&J.</p> <p>23 Q. Do you have an understanding of who hired you?</p> <p>24 A. The law firm.</p>
Page 7	Page 9
<p>1 ---</p> <p>2 PROCEEDINGS</p> <p>3 ---</p> <p>4 NOTICE TO TAKE DEPOSITION OF</p> <p>5 DR. MICHAEL KARRAM WAS MARKED AS</p> <p>6 EXHIBIT NO. 1.</p> <p>7 ---</p> <p>8 GENERAL TVT REPORT PREPARED BY</p> <p>9 MICHAEL KARRAM, M.D. WAS MARKED AS</p> <p>10 EXHIBIT NO. 2.</p> <p>11 ---</p> <p>12 CURRICULUM VITAE OF MICHAEL KARRAM,</p> <p>13 M.D. WAS MARKED AS EXHIBIT NO. 3.</p> <p>14 ---</p> <p>15 DOCUMENT ENTITLED, "RELIANCE LIST,</p> <p>16 IN ADDITION TO MATERIALS REFERENCED</p> <p>17 IN REPORT, MDL WAVE 1" WAS MARKED</p> <p>18 AS EXHIBIT NO. 4.</p> <p>19 ---</p> <p>20 MICHAEL KARRAM, M.D.</p> <p>21 being by me first duly sworn, as hereinafter certified,</p> <p>22 deposes and says as follows:</p> <p>23 EXAMINATION</p> <p>24</p>	<p>1 Q. Which law firm?</p> <p>2 A. Butler Snow.</p> <p>3 Q. Have you ever worked for that law firm before?</p> <p>4 A. No.</p> <p>5 Q. I've had marked Exhibit 1. Have you seen this</p> <p>6 document before entitled "Notice to Take Deposition of</p> <p>7 Dr. Michael Karram"?</p> <p>8 A. I have not.</p> <p>9 Q. Can you turn to page 6.</p> <p>10 A. Okay.</p> <p>11 Q. Do you see where it says "Schedule A"?</p> <p>12 A. Yes.</p> <p>13 Q. Have you ever reviewed this Schedule A before?</p> <p>14 A. No.</p> <p>15 Q. Did you bring with you No. 1, a copy of your</p> <p>16 current curriculum vitae?</p> <p>17 A. I did.</p> <p>18 Q. Do you have that with you?</p> <p>19 A. Yes.</p> <p>20 Q. Can I see that, please? Thank you.</p> <p>21 MR. ZONIES: Go ahead and mark that, please.</p> <p>22 ---</p> <p>23 CURRICULUM VITAE OF MICHAEL KARRAM,</p> <p>24 M.D., WAS MARKED AS EXHIBIT NO. 5.</p>

3 (Pages 6 to 9)

Michael Karram, M.D.

Page 10	Page 12
<p>1 - - -</p> <p>2 Q. Could you describe, please, what has been</p> <p>3 marked as Exhibit 5.</p> <p>4 A. My updated CV.</p> <p>5 Q. When did you update that CV?</p> <p>6 A. Last time was maybe about three months ago.</p> <p>7 Q. Three months ago?</p> <p>8 A. Correct.</p> <p>9 Q. Back on Exhibit 1, the Notice of Deposition,</p> <p>10 did you have any documents or bring any documents with</p> <p>11 you that are correspondence, notes, videos, CDs, DVDs</p> <p>12 with your materials that were provided to you or which</p> <p>13 relate to your opinions?</p> <p>14 A. No. The only thing I brought was my report.</p> <p>15 Q. Okay. Could I go ahead and grab that as well?</p> <p>16 A. Sure.</p> <p>17 Q. Thank you.</p> <p>18 - - -</p> <p>19 GENERAL TVT REPORT PREPARED BY</p> <p>20 MICHAEL KARRAM, M.D., WAS MARKED AS</p> <p>21 EXHIBIT NO. 6.</p> <p>22 - - -</p> <p>23 Q. Doctor, I'm handing you what has been marked</p> <p>24 as Exhibit 6, which is a copy of your report that you</p>	<p>1 A. Right.</p> <p>2 Q. What are those documents?</p> <p>3 A. Those, I think, are documents that relate to</p> <p>4 Ethicon products or information that they put in their</p> <p>5 prof ed material that we utilized for some of our</p> <p>6 cadaver courses.</p> <p>7 Q. Did you choose which documents to put on that</p> <p>8 reliance list?</p> <p>9 A. I just okayed those.</p> <p>10 Q. You okayed the list that was presented to you?</p> <p>11 A. Right.</p> <p>12 Q. Did you review every single one of those</p> <p>13 documents that are, for lack of a better word, internal</p> <p>14 Ethicon documents?</p> <p>15 MR. DIPAOLO: Object to form.</p> <p>16 A. I did not review any internal Ethicon reports.</p> <p>17 Q. You haven't reviewed any internal Ethicon</p> <p>18 documents; is that fair?</p> <p>19 A. Correct.</p> <p>20 Q. Have you reviewed any of Ethicon's design</p> <p>21 specifications for any of its products?</p> <p>22 A. Only what they incorporated in their IFUs.</p> <p>23 Q. Have you reviewed any internal Ethicon emails?</p> <p>24 A. No.</p>
Page 11	Page 13
<p>1 brought with you; is that right?</p> <p>2 A. That is correct.</p> <p>3 Q. And attached to that is a reliance list as</p> <p>4 well; is that right?</p> <p>5 A. Yes.</p> <p>6 Q. Did you prepare the reliance list?</p> <p>7 A. Yes.</p> <p>8 Q. How did you choose what materials you wanted</p> <p>9 to review?</p> <p>10 A. It was material that I used from textbooks,</p> <p>11 from journals, from previous information that I've</p> <p>12 utilized with this type of procedure, scientific data,</p> <p>13 things that I've used for lectures, talks, those types</p> <p>14 of things.</p> <p>15 Q. Have you reviewed any depositions of any</p> <p>16 Ethicon employees in preparation of your report or for</p> <p>17 this deposition?</p> <p>18 A. No.</p> <p>19 Q. Have you reviewed or attended any trials</p> <p>20 against Ethicon?</p> <p>21 A. No.</p> <p>22 Q. In your reliance materials, there are a</p> <p>23 significant number of documents marked ETH.MESH.some</p> <p>24 number; is that right?</p>	<p>1 Q. Have you reviewed any other expert witnesses'</p> <p>2 reports in this litigation?</p> <p>3 A. I reviewed Dr. Ostergard's deposition.</p> <p>4 Q. His deposition?</p> <p>5 A. Yes.</p> <p>6 Q. Anything else?</p> <p>7 A. I reviewed a Prolift report from a Dr. -- I</p> <p>8 think it's Pramudji. She's a urologist in Houston.</p> <p>9 Q. And that was the report?</p> <p>10 A. That was the report.</p> <p>11 Q. Did you review any other expert reports of</p> <p>12 either Plaintiffs' or Defendants' experts.</p> <p>13 A. No.</p> <p>14 Q. Did you review any other depositions other</p> <p>15 than Ostergard's deposition of either Plaintiffs' or</p> <p>16 Defendants' experts?</p> <p>17 A. No.</p> <p>18 Q. Why did you choose to review Ostergard's</p> <p>19 deposition?</p> <p>20 A. It was sent to me.</p> <p>21 Q. Do you know Dr. Ostergard?</p> <p>22 A. I do.</p> <p>23 Q. How well?</p> <p>24 A. Not very well now. Earlier in his career, I</p>

4 (Pages 10 to 13)

Michael Karram, M.D.

Page 14	Page 16
<p>1 knew him -- I did a rotation with him.</p> <p>2 Q. Why did you choose to review the Prolift</p> <p>3 report?</p> <p>4 A. It was sent to me.</p> <p>5 Q. Of the materials that were sent to you, did</p> <p>6 you have any follow-ups or requests for additional</p> <p>7 information?</p> <p>8 A. No.</p> <p>9 Q. If you look back at the Notice of Deposition,</p> <p>10 Exhibit 1, No. 8, any and all documents, including time</p> <p>11 sheets, invoices, time records, billing records. Did</p> <p>12 you bring anything of that nature today?</p> <p>13 A. No.</p> <p>14 Q. Have you submitted invoices for your work?</p> <p>15 A. I have.</p> <p>16 Q. Is there a reason you didn't bring those</p> <p>17 invoices today?</p> <p>18 A. I wasn't aware that I needed to bring them.</p> <p>19 Q. And that's in part because you never saw this?</p> <p>20 A. I never saw this.</p> <p>21 Q. Did you bring with you what's described in</p> <p>22 Exhibit 1, No. 10, "Any and all documents, including</p> <p>23 consulting agreements" with Ethicon?</p> <p>24 A. I did not.</p>	<p>1 Q. Is there a difference in your mind between the</p> <p>2 consulting and the preceptorships?</p> <p>3 A. Preceptorships, I would think, would be</p> <p>4 somebody who comes to my institution and watches me do</p> <p>5 surgery, or I go to their institution and watch them do</p> <p>6 surgery. That, I think, is -- I would consider</p> <p>7 different than teaching a prof ed course.</p> <p>8 Q. What is the purpose of a preceptorship?</p> <p>9 A. It's a physician is learning or has learned or</p> <p>10 has issues or questions or just wants a more experienced</p> <p>11 surgeon there when they're performing the procedure.</p> <p>12 That's the purpose of a preceptorship.</p> <p>13 Q. Were you compensated by Ethicon for</p> <p>14 preceptorships?</p> <p>15 A. Yes.</p> <p>16 Q. Did you have an agreement with Ethicon about</p> <p>17 how much you would be compensated for preceptorships?</p> <p>18 A. That was in the agreement, yes. The amount</p> <p>19 was in the agreement.</p> <p>20 Q. Was that same agreement also for professional</p> <p>21 education?</p> <p>22 A. I'm not sure. They might have been separate</p> <p>23 agreements, but it was the same type of agreement where</p> <p>24 the amount would be in the agreement.</p>
Page 15	Page 17
<p>1 MR. DIPAOLO: Object to form.</p> <p>2 Q. Did you have consulting agreements with</p> <p>3 Ethicon?</p> <p>4 MR. DIPAOLO: Object to form.</p> <p>5 A. In the past, yes.</p> <p>6 Q. How many do you think you had?</p> <p>7 MR. DIPAOLO: Object again.</p> <p>8 A. Could you describe or explain what a</p> <p>9 consulting agreement would be?</p> <p>10 Q. Sure. You've done consulting work with</p> <p>11 Ethicon; is that correct?</p> <p>12 A. If you consider teaching courses, cadaver</p> <p>13 courses, and things like that, yes.</p> <p>14 Q. Have you done preceptorships?</p> <p>15 A. Yes.</p> <p>16 Q. You've also taught professional education</p> <p>17 programs?</p> <p>18 A. Yes.</p> <p>19 Q. Have you spoken at any events on behalf of</p> <p>20 Ethicon?</p> <p>21 A. No.</p> <p>22 Q. Were you compensated by Ethicon for your time</p> <p>23 as a consultant?</p> <p>24 A. In those teaching endeavors, yes.</p>	<p>1 Q. And you've been consulting with Ethicon for</p> <p>2 how long?</p> <p>3 A. Probably in the neighborhood of -- started</p> <p>4 around 2004, 2005, something in that neighborhood, until</p> <p>5 just recently, maybe the last two or three years, when</p> <p>6 they stopped doing prof ed and preceptorships and things</p> <p>7 like that. Maybe it's been four years, the past four</p> <p>8 years.</p> <p>9 Q. Prior to 2004, did you do any work for</p> <p>10 Ethicon, consulting or preceptorships?</p> <p>11 A. Not that I'm aware of.</p> <p>12 Q. Is it your recollection that you would have</p> <p>13 annual contracts with Ethicon for purposes of your</p> <p>14 preceptorships?</p> <p>15 A. Yes.</p> <p>16 Q. Is it also your understanding that you would</p> <p>17 have annual contracts with Ethicon that would cover your</p> <p>18 professional education work?</p> <p>19 A. Yes.</p> <p>20 Q. And you're not certain if you had two</p> <p>21 different ones or if those were included in the same?</p> <p>22 A. That's correct.</p> <p>23 Q. Is it fair to say that from 2004 through --</p> <p>24 you think 2011 is fair for the last time you did it?</p>

5 (Pages 14 to 17)

Michael Karram, M.D.

Page 18	Page 20
<p>1 A. We're at 2016 now. I would say that's a rough 2 estimate, yes. 3 Q. 2011, 2012? 4 A. Something like that. 5 Q. Is it fair to say that between the years 2004 6 and 2012, approximately, that Ethicon paid you 7 compensation for work as a preceptor and as a 8 consultant? 9 MR. DIPAOLO: Object to form. 10 A. Correct. 11 Q. Do you have a sense, as you sit here today, 12 how much that amounted to each of those years? 13 A. As a total amount, no. I can say, if I 14 recollect correctly, that when I did a program, it was a 15 flat fee, something in the neighborhood of \$2,500 to 16 \$3,000 for a weekend course, which would be Friday, 17 Saturday, and sometimes Sunday morning. 18 Q. And that's for professional education? 19 A. Professional education and the preceptorships, 20 I think, were in the neighborhood of either 1,000 or 21 1,500 dollars, plus travel expenses if you had to go 22 someplace else. 23 Q. Do you have a sense of between 2004 and 2012 24 how many professional education courses you've taught on</p>	<p>1 file? 2 A. I doubt it. Maybe some of them. 3 Q. But you haven't done anything to look for 4 those? 5 A. I have not. Sorry. I have not. 6 Q. All it took was a look. 7 A. I know. 8 Q. If you look at Exhibit 1 on page 8, No. 12, 9 "All correspondence, memoranda, emails, and any other 10 documentation reflecting communications (including 11 written, electronic or oral) with any employees of 12 Defendants related to any female pelvic mesh product 13 sold by Ethicon." 14 Do you believe that you've ever corresponded, 15 either in writing or by email, with Ethicon employees 16 aside from the contract? 17 MR. DIPAOLO: Object to form. 18 Q. Aside from the -- 19 A. Where is this again on page 8? 20 Q. Page 8, No. 12. 21 A. Oh, okay. 22 Q. Do you see that? 23 A. Yes. 24 Q. So my question, Doctor, is, aside from the</p>
Page 19	Page 21
<p>1 behalf of Ethicon? 2 A. Again, as a rough estimate, I would say I 3 probably did maybe two to three a year. 4 Q. What about preceptorships? 5 A. That would be included in that two to three a 6 year. It would either be a prof ed or a preceptorship. 7 Q. When a prof ed was out of town, Ethicon would 8 also pay for your travel expenses; is that right? 9 A. That's correct. 10 Q. And you book your travel through Ethicon's 11 travel agency; is that right? 12 A. Yes. 13 Q. Aside from the consulting and the 14 preceptorships, did you receive any other compensation 15 from Ethicon? 16 A. No. 17 Q. How did you receive the contracts from 18 Ethicon? Was it electronically, or did they send them 19 to you? 20 MR. DIPAOLO: Object to form. 21 A. They sent them to me, and I would sign them 22 and send them back, and they would send me a signed 23 copy. 24 Q. You think you still have those somewhere in a</p>	<p>1 contracts we just discussed, do you believe that over 2 any time period that you've communicated in writing or 3 by email with any Ethicon employees? 4 A. No. 5 Q. If you look at No. 14, it requests any 6 documents related to professional education, including 7 PowerPoints, course materials. Do you have in your 8 possession documents like that? 9 A. No. 10 Q. Do you have any electronically, any of your 11 PowerPoint presentations that you've used for your 12 professional education? 13 A. Do I have them with me? 14 Q. Not with you. Do you have those on a computer 15 or at home or in your office? 16 A. I probably have some. 17 Q. Did you do anything to look for those and 18 bring those today? 19 A. No. 20 Q. And, again, that's because you didn't know you 21 were supposed to with this Exhibit 1? 22 A. Right. 23 Q. I notice in your report there are some what 24 appear to be screenshots --</p>

6 (Pages 18 to 21)

Michael Karram, M.D.

Page 22	Page 24
<p>1 A. Um-hmm.</p> <p>2 Q. -- or pictures of a computer.</p> <p>3 A. Um-hmm.</p> <p>4 Q. Yes?</p> <p>5 A. Yes. Sorry. Yes.</p> <p>6 Q. Can you tell me what those are?</p> <p>7 A. Those are slides that I use in presentations,</p> <p>8 and they demonstrate certain data for certain issues.</p> <p>9 Q. Are those slides that you would have actually</p> <p>10 used in your professional education?</p> <p>11 A. In some of them, yes.</p> <p>12 Q. Are those slides that you created, or were</p> <p>13 those provided to you by Ethicon?</p> <p>14 A. Actually, the slides that I used in my report</p> <p>15 were not Ethicon slides. They were somebody else's</p> <p>16 slides, another surgeon's slides.</p> <p>17 Q. Do you know whose those were?</p> <p>18 A. Mark Walters.</p> <p>19 Q. Why did you have Mark Walters' slides?</p> <p>20 A. Because we were doing a combined presentation</p> <p>21 to urogyn fellows, and he was giving the talk to the</p> <p>22 urogyn fellows, and those were some of the updated</p> <p>23 slides he had in his presentation.</p> <p>24 Q. Do you know when that presentation was given?</p>	<p>1 Exhibit 3. This was the CV that was provided to us with</p> <p>2 your report. Is that an accurate and up-to-date CV, the</p> <p>3 same as Exhibit 5?</p> <p>4 A. Didn't you give me one before?</p> <p>5 Q. You brought one.</p> <p>6 A. Oh, I brought one. Okay. Yes.</p> <p>7 Q. That's up to date?</p> <p>8 A. Um-hmm.</p> <p>9 Q. Yes?</p> <p>10 A. Yes, yes.</p> <p>11 Q. When were you first hired to work as an expert</p> <p>12 in this litigation?</p> <p>13 A. I was asked to review some records on a</p> <p>14 patient sometime last year.</p> <p>15 Q. In 2015?</p> <p>16 A. Yes. Maybe even 2014. I don't know the exact</p> <p>17 date.</p> <p>18 Q. Is it one of the three patients that you're</p> <p>19 noticed for today and tomorrow?</p> <p>20 MR. DIPOLA: Object to form.</p> <p>21 A. I think it's two patients for tomorrow. And,</p> <p>22 no, it's not.</p> <p>23 Q. So it was two patients, but not the ones who</p> <p>24 you're being deposed on?</p>
Page 23	Page 25
<p>1 A. Maybe five years ago.</p> <p>2 Q. Was that an Ethicon-sanctioned event?</p> <p>3 A. It had nothing to do with Ethicon.</p> <p>4 Q. Have you ever done any clinical trials or</p> <p>5 studies that were funded by Ethicon?</p> <p>6 A. No.</p> <p>7 Q. Even for Thermachoice?</p> <p>8 A. Correct.</p> <p>9 Q. Have you ever done any clinical studies or --</p> <p>10 clinical trials or studies related to any Ethicon</p> <p>11 device, even if not funded by Ethicon?</p> <p>12 A. No.</p> <p>13 Q. I've marked as Exhibit 2 our copy of your</p> <p>14 report in this matter.</p> <p>15 A. Okay.</p> <p>16 Q. Can you take a look at that and make sure that</p> <p>17 that's your report.</p> <p>18 A. Yes.</p> <p>19 Q. There's not a date of when you signed this.</p> <p>20 Do you have a sense, Doctor, of when you would have</p> <p>21 executed this report?</p> <p>22 A. It should have been -- let's see. We are in</p> <p>23 March. Early February.</p> <p>24 Q. I'm going to hand you what has been marked as</p>	<p>1 A. No. It was one patient, but it wasn't the</p> <p>2 ones I'm being deposed on.</p> <p>3 Q. Got it. Thank you.</p> <p>4 When were you first asked to prepare the</p> <p>5 report that's Exhibit 2 in this case?</p> <p>6 A. It would have been about four or five months</p> <p>7 ago.</p> <p>8 Q. Who asked you to do that?</p> <p>9 A. Butler Snow.</p> <p>10 Q. Tell me how long you worked on that report.</p> <p>11 A. Well, can I get a calculator?</p> <p>12 Q. Absolutely.</p> <p>13 A. I can tell you based on what I submitted.</p> <p>14 Let's see. The report was 50 -- probably about 65</p> <p>15 hours.</p> <p>16 Q. And you know that based upon how much you</p> <p>17 invoiced?</p> <p>18 A. Correct.</p> <p>19 Q. What were your total invoices?</p> <p>20 A. So far my first invoice was for 28,000. I'm</p> <p>21 pretty sure that was it. And then I just submitted</p> <p>22 another one for 9,000.</p> <p>23 Q. So you've only submitted two invoices so far?</p> <p>24 A. That's correct.</p>

7 (Pages 22 to 25)

Michael Karram, M.D.

Page 26	Page 28
<p>1 Q. The 28,000, did that cover everything up to</p> <p>2 and including the final version of your report?</p> <p>3 MR. DIPAOLA: Object to form.</p> <p>4 A. Yes.</p> <p>5 Q. Then what was the 9,000 for?</p> <p>6 A. Reviewing the same reports for today's</p> <p>7 deposition, reviewing more information on the patients</p> <p>8 that we're going to talk about tomorrow, reviewing</p> <p>9 Dr. Ostergard's deposition and some other materials that</p> <p>10 were provided.</p> <p>11 Q. And you just invoiced for that \$9,000?</p> <p>12 A. Correct.</p> <p>13 Q. Is that invoice -- does it have that type of</p> <p>14 detail that you just discussed?</p> <p>15 MR. DIPAOLA: Object to form.</p> <p>16 A. Yes.</p> <p>17 Q. It says what you were doing, and does it say</p> <p>18 how long you took reviewing Ostergard's deposition, for</p> <p>19 example?</p> <p>20 A. Yes.</p> <p>21 Q. The \$28,000, did that include your work on not</p> <p>22 just Exhibit 2 but also the three case-specific expert</p> <p>23 reports that --</p> <p>24 MR. DIPAOLA: Object to form.</p>	<p>1 A. Yes.</p> <p>2 Q. Did you do a case-specific report on</p> <p>3 Dr. Sharon Boggs?</p> <p>4 A. Yes.</p> <p>5 Q. Margaret Kirkpatrick?</p> <p>6 A. Yes.</p> <p>7 Q. Paula Kriz?</p> <p>8 A. Yes.</p> <p>9 Q. Miranda Patterson?</p> <p>10 A. Yes.</p> <p>11 Q. Any other expert reports that you've issued</p> <p>12 aside from those six and the general report?</p> <p>13 A. No.</p> <p>14 Q. Is your time, your 65 hours, does that include</p> <p>15 your case-specific report and work on all six of those</p> <p>16 cases, as well as your general report?</p> <p>17 A. Yes.</p> <p>18 Q. Does your 65 hours include work on any other</p> <p>19 cases?</p> <p>20 A. No.</p> <p>21 Q. What hourly rate do you bill?</p> <p>22 A. \$500 an hour.</p> <p>23 Q. For all types of work?</p> <p>24 A. Yes.</p>
Page 27	Page 29
<p>1 Q. -- have been provided to you?</p> <p>2 A. Two case-specific reports, yes.</p> <p>3 Q. Is your invoice broken out by which case you</p> <p>4 were working on?</p> <p>5 A. Yes.</p> <p>6 Q. Is it also separately broken out by how much</p> <p>7 time you spent on what we'll call your general report?</p> <p>8 A. Yes.</p> <p>9 Q. Do you know how much time you spent on the</p> <p>10 general report?</p> <p>11 A. No, I don't know exactly.</p> <p>12 Q. Some portion of that 65 hours, however?</p> <p>13 A. Correct.</p> <p>14 Q. If you turn back to Exhibit 1, Doctor. Do you</p> <p>15 have that in front of you?</p> <p>16 A. Yes.</p> <p>17 Q. You see in what we call the caption there are</p> <p>18 a number of cases listed?</p> <p>19 A. Correct.</p> <p>20 Q. Did you do a case-specific report on Donna</p> <p>21 Massey's case?</p> <p>22 A. Yes.</p> <p>23 Q. Did you do a case-specific report on Thelma</p> <p>24 Wright's case?</p>	<p>1 Q. Exhibit 2 is your general report; is that</p> <p>2 right?</p> <p>3 A. Yes.</p> <p>4 Q. Can you describe, please, what that is?</p> <p>5 A. This is a report that I put together</p> <p>6 discussing stress urinary incontinence, the treatments</p> <p>7 of stress urinary incontinence, the history and the</p> <p>8 evolution of the management of stress urinary</p> <p>9 incontinence, and addressing some issues as it relates</p> <p>10 to slings in the treatment of stress urinary</p> <p>11 incontinence.</p> <p>12 Q. What products would you say that report</p> <p>13 covers, what Ethicon products?</p> <p>14 A. TVT Retropubic, TVT-O, TVT Abbrevio; three.</p> <p>15 Q. Those three products?</p> <p>16 A. Those three products.</p> <p>17 Q. Does that report in your mind cover or have</p> <p>18 you issued an opinion on the TVT Secur?</p> <p>19 A. No.</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 Q. Does that report cover or have you issued an</p> <p>22 opinion on TVT Exact?</p> <p>23 A. That would be retropubic.</p> <p>24 Q. So you believe that this also does Exact in</p>

8 (Pages 26 to 29)

Michael Karram, M.D.

Page 30	Page 32
<p>1 addition to TVT Retropubic?</p> <p>2 A. Correct.</p> <p>3 Q. Have you ever used TVT Secur?</p> <p>4 A. I have.</p> <p>5 Q. When did you first start using TVT or Ethicon</p> <p>6 stress urinary incontinence products?</p> <p>7 A. 1998.</p> <p>8 Q. How were you trained?</p> <p>9 A. My brother trained me.</p> <p>10 Q. Was that in a formal course or just brothers?</p> <p>11 A. That was -- we were residents together, and we</p> <p>12 worked at the same hospital together, so it was a</p> <p>13 surgeon-surgeon training.</p> <p>14 Q. Like a preceptorship, in essence?</p> <p>15 MR. DIPAOLA: Object to the form.</p> <p>16 A. Not really. Surgeon-surgeon.</p> <p>17 Q. Where did that take place?</p> <p>18 A. Good Samaritan Hospital here in Cincinnati.</p> <p>19 Q. Have you ever published in a peer-reviewed</p> <p>20 journal?</p> <p>21 A. Yes.</p> <p>22 Q. What publication and what journal?</p> <p>23 A. You can see there are some pharmaceutical data</p> <p>24 that I published or that I was part of studies in my CV</p>	<p>1 A. Correct.</p> <p>2 Q. On your CV, Exhibit 3, you have listed under</p> <p>3 "Employment" -- do you see that section, "Employment"?</p> <p>4 A. Yes.</p> <p>5 Q. Private practice at Seven Hills Women's Health</p> <p>6 Centers --</p> <p>7 A. Yes.</p> <p>8 Q. -- from 1984 to the present, correct?</p> <p>9 A. No. I was in private practice from 1984 until</p> <p>10 1998 by myself. Then I joined Seven Hills in 1998.</p> <p>11 That's when Seven Hills came together. So then I was</p> <p>12 part of a large single-specialty group which is called</p> <p>13 Seven Hills.</p> <p>14 Q. How large is Seven Hills?</p> <p>15 A. We have 42 physicians in our group.</p> <p>16 Q. What type of practice does that range?</p> <p>17 A. It's mainly obstetrics and gynecology. We</p> <p>18 also have some breast surgeons that are part of our</p> <p>19 group.</p> <p>20 Q. It says from 1988 to 2006 you were a</p> <p>21 consultant with Hilltop Research. What is Hilltop</p> <p>22 Research?</p> <p>23 A. Hilltop Research was a research company here</p> <p>24 in town that did a lot of these studies that I was</p>
Page 31	Page 33
<p>1 list at the end. Some of those articles went into some</p> <p>2 peer-reviewed journals.</p> <p>3 Q. Are you listed as an author on those</p> <p>4 peer-reviewed publications?</p> <p>5 A. Either an author or as a cite for part of the</p> <p>6 study.</p> <p>7 Q. Which ones do you think in your CV those would</p> <p>8 be?</p> <p>9 A. The study of the third one, the transdermal</p> <p>10 estradiol, that was published in one of the menopausal</p> <p>11 journals, I think. The next one also, as was the third.</p> <p>12 The feminine hygiene study was published. A Double</p> <p>13 Blind Evaluation of Transdermal Estradiol. The third</p> <p>14 from the bottom one was. It was a testosterone study.</p> <p>15 I think those were the only ones that were in peer</p> <p>16 reviews.</p> <p>17 Q. As you sit here today, do you know if you were</p> <p>18 listed as an author in any of those peer-reviewed</p> <p>19 publications?</p> <p>20 A. I was not. Just a cite.</p> <p>21 Q. You were just an investigator at the --</p> <p>22 A. The cite, correct.</p> <p>23 Q. So you've never published as an author in any</p> <p>24 peer-reviewed journal; is that correct?</p>	<p>1 involved with. They were transdermal studies. They did</p> <p>2 dermatologic studies. We did some tampon studies.</p> <p>3 Those types of things.</p> <p>4 Q. When you did those studies as an investigator,</p> <p>5 who compensated you, if anyone, for your work?</p> <p>6 A. Hilltop.</p> <p>7 Q. And that was part of your consultancy with</p> <p>8 Hilltop?</p> <p>9 A. That's correct.</p> <p>10 Q. Why did that stop?</p> <p>11 A. They closed down, or I think they got bought</p> <p>12 out.</p> <p>13 Q. Would it be fair to say that of the research</p> <p>14 and publications we were just looking at, that most of</p> <p>15 those were through Hilltop?</p> <p>16 A. That's correct.</p> <p>17 Q. Were all of those through Hilltop?</p> <p>18 A. I would say the ones that got published, yes.</p> <p>19 Q. How were you compensated by Hilltop?</p> <p>20 A. An hourly wage.</p> <p>21 Q. How much was that hourly wage?</p> <p>22 A. You're testing my memory. I think it was in</p> <p>23 the neighborhood of \$100 an hour, \$125 an hour.</p> <p>24 Q. How did you choose which studies to get</p>

9 (Pages 30 to 33)

Michael Karram, M.D.

Page 34	Page 36
<p>1 involved in with Hilltop?</p> <p>2 A. They would ask me.</p> <p>3 Q. They would come to you and say, "We have a</p> <p>4 study on such and so. Would you like to participate?"</p> <p>5 A. That's correct.</p> <p>6 Q. Just under that in the "Employment" section,</p> <p>7 it says, "1999 to present. Consultant Ethicon Women's</p> <p>8 Health and Urology Speaker and Preceptor."</p> <p>9 A. Right, so it was probably started earlier than</p> <p>10 what I thought.</p> <p>11 Q. You think maybe it goes back to 1999?</p> <p>12 A. Correct.</p> <p>13 Q. It says to present being in 2016.</p> <p>14 A. It hasn't been that long, because they've</p> <p>15 stopped doing them.</p> <p>16 Q. Do you know why Ethicon stopped doing them?</p> <p>17 MR. DIPOLA: Objection to form.</p> <p>18 A. I would assume it's because of all the legal</p> <p>19 issues that they're dealing with.</p> <p>20 Q. So if this is accurate that you were employed</p> <p>21 by Ethicon as early as 1999, do you believe you should</p> <p>22 have contracts from back then as well?</p> <p>23 MR. DIPOLA: Object to form.</p> <p>24 A. I doubt if I have contracts back then.</p>	<p>1 Q. So when it says here in your resume "primary</p> <p>2 investigator," you were not actually a primary</p> <p>3 investigator?</p> <p>4 A. I was not actually a primary investigator.</p> <p>5 Q. You were a consultant on that?</p> <p>6 A. Correct.</p> <p>7 Q. Were you compensated by Ethicon Gynecare for</p> <p>8 your work on that presentation?</p> <p>9 A. I was compensated to go to the meeting and</p> <p>10 present, yes.</p> <p>11 Q. Your resume says under "Employment," from 1999</p> <p>12 to 2003 you were a consultant for Procter & Gamble.</p> <p>13 A. That's correct.</p> <p>14 Q. What was that related to?</p> <p>15 A. They had an osteoporosis drug called Actonel,</p> <p>16 and I was a consultant and would be on their speaker</p> <p>17 program to talk to physicians, gynecologists that deal</p> <p>18 with osteoporosis and the indications and use for</p> <p>19 Actonel in that situation.</p> <p>20 Q. Were you compensated by Procter & Gamble for</p> <p>21 your work on behalf of them for Actonel?</p> <p>22 A. Yes.</p> <p>23 Q. Do you have a sense of how much you were</p> <p>24 compensated over the years for that?</p>
Page 35	Page 37
<p>1 Q. Well, back --</p> <p>2 A. Yes. Were they issued? I had contracts, yes.</p> <p>3 Q. You would have been working with Ethicon,</p> <p>4 being compensated by Ethicon, under a contract as early</p> <p>5 as 1999, correct?</p> <p>6 A. Yes.</p> <p>7 Q. But you think it's unlikely you still have</p> <p>8 copies of those contracts?</p> <p>9 A. That's correct.</p> <p>10 Q. But you may have copies of the contracts in</p> <p>11 the later years, 2010, 2011?</p> <p>12 A. Possibly.</p> <p>13 Q. One of the studies that you list as a primary</p> <p>14 investigator on page 5 of your resume is "Clinical</p> <p>15 Evaluation of Gynecare Thermachoice III Uterine Balloon</p> <p>16 System;" is that right?</p> <p>17 A. Yes.</p> <p>18 Q. Was that a Hilltop Research project?</p> <p>19 A. No. That was an Ethicon product, but I did</p> <p>20 not actually perform. I was a consultant on that, and I</p> <p>21 was listed as the investigator, and we presented that at</p> <p>22 one of the AAGL meetings in San Francisco, and so I was</p> <p>23 asked to discuss the study at the presentation. It was</p> <p>24 a poster presentation.</p>	<p>1 A. It wouldn't be very much. Something in the</p> <p>2 neighborhood of maybe three to four thousand dollars.</p> <p>3 Q. Over the four-year period?</p> <p>4 A. Yes.</p> <p>5 Q. It lists from 2002 to 2004 that you were a</p> <p>6 consultant for Organon Pharmaceuticals. What was that</p> <p>7 for?</p> <p>8 A. That was an oral contraceptive pill.</p> <p>9 Q. Which pill?</p> <p>10 A. It was called -- I can't think of it now. It</p> <p>11 was a typical oral contraceptive pill, but I can't think</p> <p>12 of the name of it.</p> <p>13 Q. What was your job for Organon?</p> <p>14 A. I gave a talk on the pill once.</p> <p>15 Q. Did you have some special knowledge or</p> <p>16 experience with that pill?</p> <p>17 A. No.</p> <p>18 Q. Why were you giving the talk?</p> <p>19 A. Because I was a fairly busy</p> <p>20 obstetrician-gynecologist who took care of a lot of</p> <p>21 women and dealt with a lot of contraceptive issues and</p> <p>22 used many different types of contraceptive methods.</p> <p>23 Q. It also says that from '03 to 2004, you were a</p> <p>24 consultant for Pfizer Pharmaceuticals; is that right?</p>

10 (Pages 34 to 37)

Michael Karram, M.D.

Page 38	Page 40
<p>1 A. That's correct.</p> <p>2 Q. What did you do for Pfizer?</p> <p>3 A. They had Premarin cream, which is an estrogen</p> <p>4 cream, and I gave a talk on using estrogen cream for</p> <p>5 post-menopausal atrophic vaginitis.</p> <p>6 Q. Was that, again, just one talk?</p> <p>7 A. One or two.</p> <p>8 Q. Were you compensated by Pfizer for your time</p> <p>9 and work on that product?</p> <p>10 A. Yes.</p> <p>11 Q. You were also a consultant from 2003 until</p> <p>12 present for Cytec Corporation, C-y-t-e-c?</p> <p>13 A. That's correct.</p> <p>14 Q. What is Cytec Corporation?</p> <p>15 A. Cytec was a company that had, again, some</p> <p>16 contraceptives, as well as some hormone replacement</p> <p>17 therapies.</p> <p>18 Q. What did you do for Cytec?</p> <p>19 A. Gave a talk on their product.</p> <p>20 Q. One or more talks?</p> <p>21 A. One.</p> <p>22 Q. Were you compensated by Cytec for your time?</p> <p>23 A. Yes.</p> <p>24 Q. You were a consultant in 2004 to 2003 for Eli</p>	<p>1 consultant?</p> <p>2 MR. DIPOLA: Object to form.</p> <p>3 A. I was sought out, and it worked into my</p> <p>4 schedule.</p> <p>5 Q. Why subsequent to that time period did you not</p> <p>6 continue to consult for Organon, Pfizer, Cytec, or Eli</p> <p>7 Lilly?</p> <p>8 A. Most of the pharmaceutical companies either</p> <p>9 got bought out or merged with other companies, or they</p> <p>10 stopped doing programs.</p> <p>11 Q. 2004 to present, you list yourself as a</p> <p>12 medical advisory board member for Procter & Gamble,</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. Is that true as of today?</p> <p>16 A. No.</p> <p>17 Q. When did that end?</p> <p>18 A. That ended when they sold their pharmaceutical</p> <p>19 division. I'm not sure when that was, but it was</p> <p>20 probably six or seven years ago.</p> <p>21 Q. So maybe sometime around 2010ish?</p> <p>22 A. Maybe.</p> <p>23 Q. You said, Doctor, when we first met this</p> <p>24 morning that you had updated your resume about three</p>
Page 39	Page 41
<p>1 Lilly as well?</p> <p>2 A. That's correct.</p> <p>3 Q. What did you do for Eli Lilly?</p> <p>4 A. Spoke on Evista.</p> <p>5 Q. Evista?</p> <p>6 A. Evista.</p> <p>7 Q. How is that spelled?</p> <p>8 A. E-v-i-s-t-a.</p> <p>9 Q. And what --</p> <p>10 A. That's a medication for osteoporosis.</p> <p>11 Q. Is that still on the market?</p> <p>12 A. Yes.</p> <p>13 Q. What was your role for Eli Lilly? You had a</p> <p>14 speaking engagement?</p> <p>15 A. Correct.</p> <p>16 Q. Just one?</p> <p>17 A. I think just one, yes.</p> <p>18 Q. So between 2002 and 2004, you have a number of</p> <p>19 consultancy engagements with six --</p> <p>20 MR. DIPOLA: Object to form.</p> <p>21 Q. -- or so pharmaceutical or medical device</p> <p>22 companies, correct?</p> <p>23 A. Correct.</p> <p>24 Q. Why in that time frame were you so busy as a</p>	<p>1 months ago; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. These are just oversights, I assume?</p> <p>4 A. These are oversights.</p> <p>5 Q. What did you do as a medical advisory board</p> <p>6 member for Procter & Gamble?</p> <p>7 A. Talk about Actonel and meet with people and</p> <p>8 discuss marketing for Actonel.</p> <p>9 Q. What do you mean by "discuss marketing for</p> <p>10 Actonel"?</p> <p>11 A. We would meet, and they would basically have a</p> <p>12 group of doctors in the room, and we would talk about</p> <p>13 osteoporosis and the issues with osteoporosis and the</p> <p>14 competition, the different medications that are out</p> <p>15 there, and what they felt or what -- we would give them</p> <p>16 our opinion as to what we felt would be the right way to</p> <p>17 market the product to the patient that had that problem.</p> <p>18 Q. So part of your role as a member of the</p> <p>19 medical advisory board for Procter & Gamble was to help</p> <p>20 Procter & Gamble understand its target market, correct?</p> <p>21 A. No.</p> <p>22 MR. DIPOLA: Object to form.</p> <p>23 A. To understand what patients would ask or what</p> <p>24 patients verbalize when they talk about osteoporosis</p>

11 (Pages 38 to 41)

Michael Karram, M.D.

Page 42	Page 44
<p>1 with their physician.</p> <p>2 Q. So part of your role was then to help</p> <p>3 Procter & Gamble market Actonel to the correct</p> <p>4 population?</p> <p>5 MR. DIPAOLO: Object to form.</p> <p>6 A. No. To help them understand what patients ask</p> <p>7 and discuss with their physicians when they either have</p> <p>8 osteoporosis or they're at high risk for osteoporosis.</p> <p>9 We did not help them market that. We just gave them</p> <p>10 medical information.</p> <p>11 Q. You described it as you discussed marketing</p> <p>12 for Actonel, so I'm just trying to understand what you</p> <p>13 mean by the marketing for Actonel.</p> <p>14 A. We gave them that medical information. What</p> <p>15 they did with it was up to them.</p> <p>16 Q. Did you have a similar role with Eli Lilly</p> <p>17 where you would help them try to understand the market?</p> <p>18 MR. DIPAOLO: Object to form.</p> <p>19 A. No.</p> <p>20 Q. On the next item, it says, "2005 to present,</p> <p>21 Consultant, Speaker, and Preceptor for Ethicon Women's</p> <p>22 Health and Urology," correct?</p> <p>23 A. That's correct.</p> <p>24 Q. How is that different from what we were</p>	<p>1 employment as a consultant, speaker, and preceptor for</p> <p>2 American Medical Systems, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. What was your work with AMS?</p> <p>5 A. It was exactly the same. It was professional</p> <p>6 education and preceptorships.</p> <p>7 Q. For which products did you do that for AMS?</p> <p>8 A. Apogee, Perigee, Monarc, MiniArc,</p> <p>9 Anterior/Posterior Elevate, RetroArc, SPARC. I think</p> <p>10 that's it.</p> <p>11 Q. It says that you did this from 2006 to the</p> <p>12 present. Are those dates accurate?</p> <p>13 A. Well, not present. Again, they stopped as</p> <p>14 well.</p> <p>15 Q. Your work for AMS related to mesh products.</p> <p>16 Were you compensated for that work in a similar fashion</p> <p>17 as your work with Ethicon?</p> <p>18 A. Yes.</p> <p>19 MR. DIPAOLO: Object to form.</p> <p>20 Q. Did you have contracts, annual contracts, with</p> <p>21 AMS?</p> <p>22 A. Yes.</p> <p>23 Q. Would you say that you did more or less work</p> <p>24 with AMS than you did with Ethicon?</p>
Page 43	Page 45
<p>1 reviewing earlier, which was "1999 to present,</p> <p>2 Consultant for Ethicon Women's Health and Urology," if</p> <p>3 it is?</p> <p>4 A. Earlier usually it just meant that Ethicon may</p> <p>5 send some surgeons in to watch me operate, and that was</p> <p>6 all. Then as -- the "Consultant, Speaker," that was</p> <p>7 more prof ed, and preceptorships when I went to</p> <p>8 preceptor people.</p> <p>9 Q. And so --</p> <p>10 A. Whereas, earlier it was just they would come</p> <p>11 watch me in the OR.</p> <p>12 Q. So you think the distinction would be from</p> <p>13 2005 to present, that that was more professional</p> <p>14 education and your traveling to do preceptorships?</p> <p>15 MR. DIPAOLO: Object to form.</p> <p>16 A. Yes.</p> <p>17 Q. Again, that says "to present," but is that not</p> <p>18 accurate?</p> <p>19 A. That's not accurate.</p> <p>20 Q. Is that also something that you think ended in</p> <p>21 about 2011, 2012?</p> <p>22 A. I think the last -- maybe the last program I</p> <p>23 gave was 2010 or 2011, yes.</p> <p>24 Q. The next line down, it discusses your</p>	<p>1 MR. DIPAOLO: Object to form.</p> <p>2 A. I'd say about equal.</p> <p>3 Q. About equal?</p> <p>4 A. Um-hmm.</p> <p>5 Q. Are there any other consultancies,</p> <p>6 preceptorships, or work that you've done with a</p> <p>7 pharmaceutical company or a medical device company that</p> <p>8 aren't on your resume?</p> <p>9 A. Actually, Cytec now is Hologic, H-o-l-o-g-i-c.</p> <p>10 So that would be the old Cytec-Hologic, but they are</p> <p>11 still the same. So that would be in the same realm.</p> <p>12 And to answer your question, no, I don't think there's</p> <p>13 any other consulting agreements that I'm involved with</p> <p>14 right now that is not listed here.</p> <p>15 Q. Or have been involved with over your career?</p> <p>16 A. Correct.</p> <p>17 Q. Have you ever had your deposition taken</p> <p>18 before?</p> <p>19 A. Yes.</p> <p>20 Q. How many times?</p> <p>21 A. Four.</p> <p>22 Q. Can you briefly describe each of those.</p> <p>23 A. Sure. The first one was as a resident. It</p> <p>24 was -- I was a second year resident in obstetrics and</p>

12 (Pages 42 to 45)

Michael Karram, M.D.

Page 46	Page 48
<p>1 gynecology. It was involving an obstetrics case where a</p> <p>2 lady had a vasa previa, and her baby had some</p> <p>3 complications, and I was the resident involved in the</p> <p>4 delivery of the baby, and it was a lawsuit related to</p> <p>5 that case.</p> <p>6 Q. Was it a medical malpractice lawsuit?</p> <p>7 A. Yes.</p> <p>8 Q. And you were a named defendant?</p> <p>9 A. No. I was just a resident. I wasn't named in</p> <p>10 the case.</p> <p>11 Q. What was the outcome of that case?</p> <p>12 A. The baby had some neurologic issues.</p> <p>13 Q. Do you know what the legal outcome was?</p> <p>14 A. I think it was settled for an amount of money.</p> <p>15 Q. Was your care alleged to be substandard in</p> <p>16 that case?</p> <p>17 MR. DIPOLA: Object to form.</p> <p>18 A. No.</p> <p>19 Q. What about the second?</p> <p>20 A. The second one was I was involved in a</p> <p>21 delivery of a baby that had a brachial plexus injury.</p> <p>22 Q. So that was a medical malpractice case?</p> <p>23 A. Correct.</p> <p>24 Q. Were you a defendant in that case?</p>	<p>1 A. I was deposed as an expert witness in a case</p> <p>2 in Wyoming.</p> <p>3 Q. What type of case?</p> <p>4 A. It was a bowel injury at the time of a vaginal</p> <p>5 hysterectomy.</p> <p>6 Q. On whose behalf were you an expert?</p> <p>7 A. I was an expert on the defense.</p> <p>8 Q. When was that?</p> <p>9 A. 2012, I think. I'm not quite sure.</p> <p>10 Q. Who hired you for that work?</p> <p>11 A. A law firm in Cheyenne, Wyoming.</p> <p>12 Q. Do you know the name of the firm?</p> <p>13 A. I don't know that offhand.</p> <p>14 Q. Do you know the name of the plaintiff in that</p> <p>15 case?</p> <p>16 A. I don't remember.</p> <p>17 Q. Do you know what the outcome was?</p> <p>18 A. Yes.</p> <p>19 Q. What was the outcome?</p> <p>20 A. It was a defense verdict.</p> <p>21 Q. That went to trial, that case?</p> <p>22 A. Yes.</p> <p>23 Q. Did you testify at trial?</p> <p>24 A. Yes.</p>
Page 47	Page 49
<p>1 A. Yes.</p> <p>2 Q. When was that?</p> <p>3 A. 2010.</p> <p>4 Q. Is that case still ongoing?</p> <p>5 A. No.</p> <p>6 Q. You were deposed in that case?</p> <p>7 A. Yes.</p> <p>8 Q. What was the outcome of that case?</p> <p>9 A. That went to trial, and it was a defense</p> <p>10 verdict -- or a plaintiff's verdict. I'm sorry.</p> <p>11 Q. Where did that trial occur?</p> <p>12 A. Cincinnati.</p> <p>13 Q. Do you know what the verdict amount was?</p> <p>14 A. 800,000.</p> <p>15 Q. Do you know who the attorney for the plaintiff</p> <p>16 was?</p> <p>17 A. John Holschuh, I think, is his name.</p> <p>18 Q. What was the plaintiff's name?</p> <p>19 A. Caminiti.</p> <p>20 Q. I'm sorry?</p> <p>21 A. Caminiti.</p> <p>22 Q. Caminiti?</p> <p>23 A. Is her last name, yes.</p> <p>24 Q. What was your third deposition?</p>	<p>1 Q. Do you know if that was in a federal court or</p> <p>2 state court?</p> <p>3 A. I would assume state. I don't know.</p> <p>4 Q. Did you issue a report in that case?</p> <p>5 A. A written report like this (indicating)?</p> <p>6 Q. Yes.</p> <p>7 A. No.</p> <p>8 Q. But you were deposed?</p> <p>9 A. I was deposed here in Cincinnati.</p> <p>10 Q. And also gave trial testimony?</p> <p>11 A. Correct.</p> <p>12 Q. Do you think that trial was in 2012?</p> <p>13 A. I'm trying to think where it was in</p> <p>14 relationship to the brachial plexus. It was after 2010.</p> <p>15 I don't know the exact date.</p> <p>16 Q. What was the fourth deposition?</p> <p>17 A. This one.</p> <p>18 Q. In the Wyoming trial in approximately 2012,</p> <p>19 you were an expert witness; is that right?</p> <p>20 A. That's correct.</p> <p>21 Q. And that was for the defense in that case?</p> <p>22 A. Yes.</p> <p>23 Q. Was that a medical doctor that you were</p> <p>24 testifying on behalf of?</p>

13 (Pages 46 to 49)

Michael Karram, M.D.

Page 50	Page 52
<p>1 A. Yes.</p> <p>2 Q. Other than that Wyoming case and this work</p> <p>3 that we're discussing today and tomorrow, have you done</p> <p>4 any other expert witness work?</p> <p>5 A. I've reviewed cases, yes.</p> <p>6 Q. Have you ever written a report as an expert</p> <p>7 witness other than the report we're looking at today?</p> <p>8 A. No.</p> <p>9 Q. How often would you say that you in the past</p> <p>10 year have looked at cases as you described it as an</p> <p>11 expert?</p> <p>12 MR. DIPAOLA: Object to form.</p> <p>13 A. I looked at a case two or three months ago,</p> <p>14 and this would be -- what we're doing now would be the</p> <p>15 second case this year.</p> <p>16 Q. In prior years, was it something that you did</p> <p>17 a lot of work on?</p> <p>18 A. Not a lot.</p> <p>19 Q. You don't hold yourself out as an expert</p> <p>20 witness in FDA regulations related to medical devices,</p> <p>21 do you?</p> <p>22 A. No.</p> <p>23 Q. You don't hold yourself out as an expert</p> <p>24 witness in marketing of medical devices, do you?</p>	<p>1 A. No.</p> <p>2 Q. Would you consider yourself an expert in</p> <p>3 statistics?</p> <p>4 A. Far from it.</p> <p>5 Q. Would you consider yourself an expert in</p> <p>6 epidemiology?</p> <p>7 A. No.</p> <p>8 Q. What would you consider to be Level 1</p> <p>9 evidence?</p> <p>10 A. That would be a strong meta-analysis,</p> <p>11 randomized control trials. Those would be probably the</p> <p>12 two strongest Level 1 evidence.</p> <p>13 Q. You believe a meta-analysis to be Level 1</p> <p>14 evidence, correct?</p> <p>15 A. If you look at a number of studies, yes.</p> <p>16 Q. What do you mean?</p> <p>17 A. I mean, if you look at a large number of</p> <p>18 studies on the same subject and you analyze them, yes.</p> <p>19 Q. Does it matter if the studies that are</p> <p>20 included in the meta-analysis are observational studies</p> <p>21 or randomized control studies?</p> <p>22 MR. DIPAOLA: Object to form.</p> <p>23 A. Randomized controls would be stronger.</p> <p>24 Q. Do you believe a meta-analysis of</p>
Page 51	Page 53
<p>1 A. No.</p> <p>2 Q. You're not an expert in biomaterials; is that</p> <p>3 correct?</p> <p>4 A. No, that's correct.</p> <p>5 Q. You're not an expert in pathology?</p> <p>6 A. I would consider myself not an expert in</p> <p>7 pathology.</p> <p>8 Q. Would you consider yourself an expert in</p> <p>9 drafting instructions for use or IFUs?</p> <p>10 MR. DIPAOLA: Object to form.</p> <p>11 A. No.</p> <p>12 Q. Would you consider yourself or hold yourself</p> <p>13 out as an expert in medical device industry practices?</p> <p>14 MR. DIPAOLA: Object to form.</p> <p>15 A. Could you elaborate on that question?</p> <p>16 Q. Sure. Would you consider yourself or hold</p> <p>17 yourself out as an expert in the development of medical</p> <p>18 devices?</p> <p>19 A. No.</p> <p>20 Q. Would you consider yourself an expert in</p> <p>21 design of medical devices?</p> <p>22 MR. DIPAOLA: Object to form.</p> <p>23 A. No.</p> <p>24 Q. Have you ever designed a clinical study?</p>	<p>1 observational studies is equivalent level of evidence to</p> <p>2 a randomized control trial?</p> <p>3 A. No.</p> <p>4 Q. Which is stronger?</p> <p>5 A. The randomized control trial.</p> <p>6 Q. Do you understand or have an appreciation of</p> <p>7 the difference between a relative risk and an odds</p> <p>8 ratio?</p> <p>9 MR. DIPAOLA: Object to form.</p> <p>10 A. Somewhat.</p> <p>11 Q. What is the difference?</p> <p>12 A. Relative risk, it gives you the chance of</p> <p>13 developing a problem when you're looking at two</p> <p>14 statistics or two varying techniques or procedures. And</p> <p>15 odds ratio is what your chances of developing a problem</p> <p>16 is in relationship to whatever problem you're looking</p> <p>17 at.</p> <p>18 Q. What did you do to prepare for today's</p> <p>19 deposition?</p> <p>20 A. Reviewed the records of the patients that</p> <p>21 we're going to be talking about tomorrow. Reviewed my</p> <p>22 report. Obviously did not update my CV correctly.</p> <p>23 Looked at some information that was provided by Butler</p> <p>24 Snow. Reviewed some articles that I've looked at in the</p>

14 (Pages 50 to 53)

Michael Karram, M.D.

Page 54	Page 56
<p>1 past. Maybe read some abstracts on some of those</p> <p>2 articles, textbooks that I used when I prepared my</p> <p>3 report. That's really it.</p> <p>4 Q. Did you meet with counsel for Ethicon?</p> <p>5 A. With Ethicon?</p> <p>6 Q. Yes.</p> <p>7 A. Would that be Doug?</p> <p>8 Q. Yes.</p> <p>9 A. Yes.</p> <p>10 Q. Did you meet with any other attorneys other</p> <p>11 than Doug?</p> <p>12 A. No.</p> <p>13 Q. When did you meet with Ethicon's counsel?</p> <p>14 MR. DIPOLA: Object to form.</p> <p>15 A. We met last Tuesday.</p> <p>16 Q. And for how long?</p> <p>17 A. About three hours.</p> <p>18 Q. And before last Tuesday -- is that the last</p> <p>19 time you met with him other than this morning?</p> <p>20 A. Correct.</p> <p>21 Q. Prior to that, had you met with him in person</p> <p>22 before or by phone?</p> <p>23 A. Yes.</p> <p>24 Q. When?</p>	<p>1 of vaginal hysterectomy in minimally invasive surgery</p> <p>2 and pelvic floor surgery.</p> <p>3 Q. Did that include discussions about mesh?</p> <p>4 A. No.</p> <p>5 Q. We discussed earlier a number of depositions</p> <p>6 and trial testimony that you've given. Do you recall</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. Other than the brachial plexus case, have you</p> <p>10 ever been sued in any way?</p> <p>11 A. No.</p> <p>12 Q. In your expert report, you say you've</p> <p>13 performed over 2,000 slings.</p> <p>14 A. That's correct.</p> <p>15 Q. Is that from 1999 until present?</p> <p>16 A. Yes.</p> <p>17 Q. Do you have a sense of the breakdown in your</p> <p>18 practice over time of which slings you used over the</p> <p>19 years?</p> <p>20 A. You mean specific slings or types of slings?</p> <p>21 The main types of slings are retropubic slings and</p> <p>22 transobturator slings. And I would say through my</p> <p>23 career, I've probably done maybe 65 to 70 percent</p> <p>24 transobturator slings, and the other 20, 25 percent</p>
Page 55	Page 57
<p>1 A. By phone, I can't tell you exactly when, but</p> <p>2 we've had phone conversations, and the first time I met</p> <p>3 Doug was at my office, and that was about two years ago</p> <p>4 when we were looking at -- I think when we were looking</p> <p>5 at reviewing some cases.</p> <p>6 Q. Is that the first time you were approached to</p> <p>7 work on Ethicon mesh cases, about two years ago?</p> <p>8 A. Yes.</p> <p>9 Q. And it was Doug that met you?</p> <p>10 A. Correct.</p> <p>11 (Short recess taken.)</p> <p>12 Q. Doctor, on Exhibit 2, which is a copy of your</p> <p>13 report, you have there "Education, Training and</p> <p>14 Experience" on the first page. Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. It says 2013 and 2015, down at the bottom</p> <p>17 there. You were a presenter at an AUGS meeting, A-U-G-S</p> <p>18 meeting; is that correct?</p> <p>19 A. Yes.</p> <p>20 Q. Do you know what those two presentations were?</p> <p>21 A. Yes. The first one was on -- I'm trying to</p> <p>22 think what we presented on. It was a round table</p> <p>23 discussion on -- oh, the 2015 was a -- both of them were</p> <p>24 round table discussions on the indication for or the use</p>	<p>1 would be retropubic.</p> <p>2 Q. And you use both AMS and Ethicon's products,</p> <p>3 correct?</p> <p>4 A. I do, yes.</p> <p>5 Q. Is that current today? You still use both?</p> <p>6 A. Actually, AMS is taking their products off the</p> <p>7 market. But, yes, as of, I think, March 31st, they</p> <p>8 still have product on the shelf.</p> <p>9 Q. Did you have a particular percentage of use of</p> <p>10 AMS versus Ethicon products?</p> <p>11 MR. DIPOLA: Object to form.</p> <p>12 A. I can't really give you a percentage. It's</p> <p>13 more patient specific.</p> <p>14 Q. Other than AMS and Ethicon slings, have you</p> <p>15 used any other slings?</p> <p>16 A. I've tried a few, but I've never used any</p> <p>17 on -- more than those on a regular basis.</p> <p>18 Q. Why did you choose to use Ethicon and AMS</p> <p>19 slings?</p> <p>20 A. Ethicon slings I chose to use because they</p> <p>21 were the first slings that came out, in my experience.</p> <p>22 And in looking at the data that they had behind their</p> <p>23 slings, I felt that it was the sling that had the best</p> <p>24 data out there, and so that's why I continue to use</p>

15 (Pages 54 to 57)

Michael Karram, M.D.

Page 58	Page 60
<p>1 those slings.</p> <p>2 Q. Why do you use AMS slings?</p> <p>3 A. AMS makes a -- or did make a single-incision</p> <p>4 sling called MiniArc; and of the single-incision slings,</p> <p>5 MiniArc in my hands seemed to work the best, and in my</p> <p>6 patient population seemed to give me the best results.</p> <p>7 So I use that.</p> <p>8 There's a certain subset of population that</p> <p>9 I'm doing a transobturator approach on; and in that</p> <p>10 situation, under certain circumstances, I'll use an</p> <p>11 outside-in transobturator, which is their Monarc, versus</p> <p>12 an inside-out. And I use their SPARC, which is a</p> <p>13 top-down retropubic.</p> <p>14 Q. Would you say you have a particular preference</p> <p>15 for the SPARC as compared to the TVT?</p> <p>16 MR. DIPAOLO: Object to form.</p> <p>17 A. My go-to retropubic sling is a TVT Exact</p> <p>18 today.</p> <p>19 Q. What is your go-to obturator sling today?</p> <p>20 A. It's equal between a Monarc and TVT Abbrevio.</p> <p>21 Q. What informs your choice of whether to use the</p> <p>22 Monarc or the Abbrevio?</p> <p>23 MR. DIPAOLO: Object to form.</p> <p>24 A. It has to do with the type of incontinence</p>	<p>1 Q. When was the last time you think you did a</p> <p>2 Burch?</p> <p>3 A. 2000 something, in the early 2000s, I'd say.</p> <p>4 Q. You would agree that the Burch today is a safe</p> <p>5 and effective procedure, correct?</p> <p>6 MR. DIPAOLO: Object to form.</p> <p>7 A. Yes.</p> <p>8 Q. What is in your decision-making process when</p> <p>9 you're choosing whether to do a retropubic or an</p> <p>10 obturator procedure?</p> <p>11 A. I'll use an obturator procedure for somebody</p> <p>12 that I would consider a simple, if there is such a</p> <p>13 thing, hypermobile urethra that does not have intrinsic</p> <p>14 sphincter deficiency, has not failed a previous surgery.</p> <p>15 That would be an obturator.</p> <p>16 Q. So for an ISD patient, you would not choose an</p> <p>17 obturator approach; is that correct?</p> <p>18 A. In the majority of cases.</p> <p>19 Q. Or for a patient who has a more complex</p> <p>20 presentation, you would not necessarily choose an</p> <p>21 obturator approach?</p> <p>22 MR. DIPAOLO: Object to form.</p> <p>23 A. Not so much complex as the situation.</p> <p>24 Q. What do you mean by that?</p>
Page 59	Page 61
<p>1 they have, the weight of the patient, if they've had</p> <p>2 previous surgeries or not, the anatomy of the obturator</p> <p>3 space. Those are probably the four biggest.</p> <p>4 Q. Are there any other surgical procedures that</p> <p>5 you've used to treat stress urinary incontinence apart</p> <p>6 from the TVT and AMS products?</p> <p>7 A. Today or in my past?</p> <p>8 Q. Let's start with today.</p> <p>9 A. Today, that, and there's a rare occasion where</p> <p>10 we'll use a -- or I will use a pubofascial sling.</p> <p>11 Q. What would that rare occasion be today?</p> <p>12 A. In a patient who absolutely does not want to</p> <p>13 have a mesh product, in a patient who has had multiple</p> <p>14 mesh slings and failed, in somebody who has a very rigid</p> <p>15 urethra and so we need to do something more at the</p> <p>16 bladder neck than at the midurethra.</p> <p>17 Q. How often would you say you've done that type</p> <p>18 of surgery in the past year?</p> <p>19 A. In the past year, I don't think I've done one.</p> <p>20 I think the last one was last year.</p> <p>21 Q. In 1999, prior to your starting to use the TVT</p> <p>22 Retropubic, how were you treating stress urinary</p> <p>23 incontinence in your practice?</p> <p>24 A. Burch.</p>	<p>1 A. Well, if somebody had ISD but they had mixed</p> <p>2 incontinence where they had a very, very significant</p> <p>3 amount of overactive bladder, even though from an</p> <p>4 anatomical standpoint, a retropubic might be the better</p> <p>5 procedure, but you might increase her overactive bladder</p> <p>6 symptoms, so I would probably use a transobturator</p> <p>7 approach and put it in a little tighter.</p> <p>8 Q. You would tension in the tape a little</p> <p>9 tighter?</p> <p>10 A. In that situation, yes.</p> <p>11 Q. Do you believe the TVT is more efficacious for</p> <p>12 intrinsic sphincter deficiency?</p> <p>13 A. I do.</p> <p>14 Q. Do you base that on any scientific literature,</p> <p>15 or is that based on your own experience?</p> <p>16 A. Both.</p> <p>17 Q. If Ethicon was aware that the obturator was</p> <p>18 not as efficacious for treatment of intrinsic sphincter</p> <p>19 deficiency as compared to the retropubic, do you believe</p> <p>20 that's something Ethicon should have informed physicians</p> <p>21 of?</p> <p>22 MR. DIPAOLO: Object to form.</p> <p>23 A. No.</p> <p>24 Q. Doctor, in your report -- I'm sorry. There</p>

16 (Pages 58 to 61)

Michael Karram, M.D.

Page 62	Page 64
<p>1 aren't page numbers on my version.</p> <p>2 A. That's okay.</p> <p>3 Q. But there are a number of diagrams --</p> <p>4 A. Yes.</p> <p>5 Q. -- that start with Kelly plication. Do you</p> <p>6 see that?</p> <p>7 A. Yes.</p> <p>8 Q. Where did you get that diagram?</p> <p>9 A. That was from a -- actually, on the last page,</p> <p>10 all my diagrams are from the Atlas of Pelvic Anatomy and</p> <p>11 Gynecology, Surgery for Urinary Incontinence and from</p> <p>12 the Urogynecology and Reconstructive Surgery book. All</p> <p>13 the diagrams are from those two sites.</p> <p>14 Q. Those are all books written in part by your</p> <p>15 brother; is that right?</p> <p>16 A. The Baggish and Karram Atlas, yes. The</p> <p>17 urogyn, that was a synopsis of multiple different</p> <p>18 authors. Some of those are his, and some of them are</p> <p>19 from other authors within that textbook.</p> <p>20 Q. The next diagram is for the MMK repair.</p> <p>21 A. Yes.</p> <p>22 Q. Then what is the next diagram?</p> <p>23 A. Hang on a second. So the MMK is</p> <p>24 Marshall-Marchetti-Krantz, and then the next is the</p>	<p>1 A. A fascial sling.</p> <p>2 Q. A fascial sling?</p> <p>3 A. Yes.</p> <p>4 Q. And you say there that the TVT -- the third</p> <p>5 line down, it starts with, "It has the advantages." Do</p> <p>6 you see that sentence?</p> <p>7 A. Yes.</p> <p>8 Q. You say, "The TVT has the advantages of a</p> <p>9 minimally invasive outpatient procedure and results that</p> <p>10 are comparable to the Burch procedure." Do you believe</p> <p>11 that the TVT has results that are comparable to the</p> <p>12 Burch procedure?</p> <p>13 A. Yes.</p> <p>14 Q. Two pages later you have a photo of a</p> <p>15 retropubic TVT.</p> <p>16 A. That's correct.</p> <p>17 Q. And then after that, you say "(also showing</p> <p>18 the loose tensioning technique)." Is that right?</p> <p>19 A. Yes.</p> <p>20 Q. What do you mean by "loose tensioning</p> <p>21 technique"?</p> <p>22 MR. DIPOLA: Object to form.</p> <p>23 A. To leave the sling under the urethra very</p> <p>24 loosely and leave a space in between the urethra and the</p>
Page 63	Page 65
<p>1 Burch. It says, "Photo of a Burch repair."</p> <p>2 Q. That's a Burch repair that you're showing</p> <p>3 there?</p> <p>4 A. Yes.</p> <p>5 Q. Then on the next page is a combined Burch and</p> <p>6 paravaginal repair?</p> <p>7 A. That's correct.</p> <p>8 Q. Have you ever performed that procedure?</p> <p>9 A. Yes.</p> <p>10 Q. When is the last time you think you did that?</p> <p>11 A. Before 2000.</p> <p>12 Q. Then the next one is another picture of a</p> <p>13 Burch repair, correct?</p> <p>14 A. Yes.</p> <p>15 Q. What's the difference between that photo of a</p> <p>16 Burch repair and the one two pages earlier?</p> <p>17 A. Just another photo. There's nothing -- the</p> <p>18 photo -- the first one is tied, and you can see that the</p> <p>19 way the first one is tied, the first photo, it ties</p> <p>20 across the ligament; whereas, in the second photo, you</p> <p>21 actually pass the sutures through and tie on top of the</p> <p>22 ligament, which is the better way to do it.</p> <p>23 Q. You say a few pages later in your report</p> <p>24 there's a picture of a -- a photo of a fascial sling.</p>	<p>1 sling.</p> <p>2 Q. Do you believe that that's how the tensioning</p> <p>3 is described in the IFU?</p> <p>4 MR. DIPOLA: Object to form.</p> <p>5 A. Actually, I'm not sure how it's described in</p> <p>6 the IFU.</p> <p>7 Q. You agree that a complication of -- a</p> <p>8 well-recognized complication with TVT is bladder</p> <p>9 perforation, correct?</p> <p>10 MR. DIPOLA: Objection to form.</p> <p>11 A. Yes.</p> <p>12 Q. You also opine that routine cystoscopy is</p> <p>13 performed on all sling procedures, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Do you think that is a requirement that should</p> <p>16 be done for standard of care on all TVT procedures?</p> <p>17 MR. DIPOLA: Object to form.</p> <p>18 A. In my opinion, yes.</p> <p>19 Q. Do you believe that should be noted as a</p> <p>20 requirement in the instructions for use?</p> <p>21 MR. DIPOLA: Object to form.</p> <p>22 A. No.</p> <p>23 Q. Do you believe that there is a certain</p> <p>24 population of physicians who are using the TVT device</p>

17 (Pages 62 to 65)

Michael Karram, M.D.

Page 66	Page 68
<p>1 who may not be as skilled at cystoscopy?</p> <p>2 MR. DIPAOLA: Object to form.</p> <p>3 A. No.</p> <p>4 Q. Doctor, I asked you earlier whether or not you</p> <p>5 had been involved in any other lawsuits other than the</p> <p>6 four that we've discussed. Do you recall that?</p> <p>7 A. Yes.</p> <p>8 Q. You've been involved in one other lawsuit that</p> <p>9 I found as well involving the Department of Justice. Do</p> <p>10 you recall that?</p> <p>11 A. Yes.</p> <p>12 Q. An action was brought against you by the</p> <p>13 United States of America, correct?</p> <p>14 A. Correct.</p> <p>15 Q. And it was for violation of the antitrust act,</p> <p>16 correct?</p> <p>17 A. It was in their opinion, yes.</p> <p>18 Q. The United States of America brought a lawsuit</p> <p>19 against you and a number of other doctors alleging that</p> <p>20 you had conspired with those doctors to inhibit</p> <p>21 competition in the Cincinnati area, correct?</p> <p>22 A. That was their opinion, yes. And just for</p> <p>23 clarification, I thought when you asked me that</p> <p>24 question, you were talking about medical malpractice.</p>	<p>1 States versus Federation of Physicians and Dentists, et</p> <p>2 al.," correct?</p> <p>3 A. Correct.</p> <p>4 Q. This is a lawsuit, if you look at the second</p> <p>5 paragraph, filed on June 24th, 2005, correct?</p> <p>6 A. Correct.</p> <p>7 Q. You were a defendant in this lawsuit, correct?</p> <p>8 A. Correct.</p> <p>9 Q. It says, "On June 24th, 2005, the United</p> <p>10 States filed a complaint alleging that the Federation of</p> <p>11 Physicians and Dentists (Federation), Dr. Michael</p> <p>12 Karram, Dr. Warren Metherd, and Dr. James Wendel</p> <p>13 conspired with other OB-GYN members to increase fees</p> <p>14 paid by commercial insureds to Federation members in</p> <p>15 violation of the Sherman Act Section 1." Did I read</p> <p>16 that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. You reached, along with the other two doctors,</p> <p>19 a settlement with the United States of this antitrust</p> <p>20 case, correct?</p> <p>21 A. That's correct.</p> <p>22 Q. If you look on the second page, the bottom</p> <p>23 left, paragraph 1, "Nature and Purpose of the</p> <p>24 Proceedings." Do you see where I am?</p>
Page 67	Page 69
<p>1 Q. Understood. So let me back up and say are</p> <p>2 there any other lawsuits in which you've been involved</p> <p>3 even outside of the medical realm all together?</p> <p>4 A. Not that I'm aware of.</p> <p>5 MR. ZONIES: So we'll go ahead and mark this</p> <p>6 as Exhibit 7.</p> <p>7 ---</p> <p>8 FEDERAL REGISTER, VOLUME 70, NO.</p> <p>9 147, TUESDAY, AUGUST 2, 2005,</p> <p>10 NOTICES, PAGES 44376-44387 WAS</p> <p>11 MARKED AS EXHIBIT NO. 7.</p> <p>12 ---</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. We've marked this as Exhibit 7, Doctor.</p> <p>15 A. Okay.</p> <p>16 Q. Doctor, I've handed you a document. You can</p> <p>17 see at the top it's from the Federal Register, and it's</p> <p>18 notices dated August 2nd, 2005; is that right?</p> <p>19 A. Yes.</p> <p>20 Q. If you look at Department of Justice in the</p> <p>21 right-hand column -- do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And this is the "Antitrust Division Proposed</p> <p>24 Final Judgment and Competitive Impact Statement, United</p>	<p>1 A. Yes.</p> <p>2 Q. And this is in the Federal Register, Volume</p> <p>3 70, No. 147, page 44377; is that right?</p> <p>4 A. Yes.</p> <p>5 Q. It says, "The Plaintiff filed this civil</p> <p>6 antitrust Complaint on June 24th, 2005, in the United</p> <p>7 States District Court for the Southern District of Ohio,</p> <p>8 Western Division, alleging that Drs. Warren Metherd,</p> <p>9 Michael Karram, James Wendel (the Settling Physician</p> <p>10 Defendants), obstetrician-gynecologist physicians,</p> <p>11 (OB-GYNs) practicing in Cincinnati, Ohio, participated</p> <p>12 in a conspiracy that has unreasonably restrained</p> <p>13 interstate trade and commerce in violation of Section 1</p> <p>14 of the Sherman Act." Is that right?</p> <p>15 A. Is that what it says?</p> <p>16 Q. Yes.</p> <p>17 A. Yes.</p> <p>18 Q. That's the complaint brought by -- the</p> <p>19 plaintiff in this case is actually the United States of</p> <p>20 America, correct?</p> <p>21 A. Correct.</p> <p>22 Q. The Department of Justice?</p> <p>23 A. Correct.</p> <p>24 MR. DIPAOLA: Objection to relevance and form</p>

18 (Pages 66 to 69)

Michael Karram, M.D.

Page 70	Page 72
<p>1 to this whole line of questioning.</p> <p>2 Q. The document goes on to state, "As alleged in</p> <p>3 the complaint, this agreement has artificially raised</p> <p>4 fees paid by health insurers to OB-GYNs in the</p> <p>5 Cincinnati area that are ultimately borne by employers</p> <p>6 and their employees." That was the allegation in the</p> <p>7 complaint, correct?</p> <p>8 A. Correct.</p> <p>9 Q. And you settled that complaint, correct?</p> <p>10 A. Correct. A consent decree, if that's a</p> <p>11 settlement, yes.</p> <p>12 Q. And under that consent decree, you had a</p> <p>13 continuing obligation for a period of ten years</p> <p>14 following the date of entry of the final judgment to</p> <p>15 certify annually to the United States of America that</p> <p>16 you were complying with the terms of the consent decree,</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. Have you done that for ten years?</p> <p>20 A. And it's over, yes.</p> <p>21 Q. It ended in 2015?</p> <p>22 A. Correct.</p> <p>23 Q. The gist of this complaint was effectively</p> <p>24 that you and other physicians had gotten together in an</p>	<p>1 trying to get better reimbursements?</p> <p>2 A. The letters came from the federation, and we</p> <p>3 met with insurance companies, yes, on an individual</p> <p>4 basis, representing our practices individually, not</p> <p>5 together.</p> <p>6 Q. As part of the allegations in this complaint,</p> <p>7 the United States, the Department of Justice, alleges</p> <p>8 that from December of 2002 through March of 2003, that</p> <p>9 you, Dr. Karram, and Dr. Wendel's large OB-GYN groups</p> <p>10 spearheaded federation member group's attempts to</p> <p>11 renegotiate their contracts with Anthem and Humana,</p> <p>12 correct?</p> <p>13 MR. DIPOLA: Same objection.</p> <p>14 A. That's what they said, but that's not what</p> <p>15 happened.</p> <p>16 Q. The allegation specifically quote emails from</p> <p>17 you to a Ms. Odenkirk. Is she with the federation?</p> <p>18 A. That's correct.</p> <p>19 Q. And one of the quotes is, "I agree with</p> <p>20 Warren. We need to get everyone moving faster and to</p> <p>21 become more persistent; otherwise, they will not get</p> <p>22 increases in 2003. I'm sure that is what ChoiceCare is</p> <p>23 doing."</p> <p>24 MR. DIPOLA: Object. Is there a question?</p>
Page 71	Page 73
<p>1 effort to get health insurance companies to provide</p> <p>2 higher reimbursement for procedures that you were</p> <p>3 performing, correct?</p> <p>4 MR. DIPOLA: Object to form.</p> <p>5 A. Incorrect.</p> <p>6 Q. What do you understand this complaint to be,</p> <p>7 the activity that this complaint was addressing?</p> <p>8 A. There was an organization called the</p> <p>9 Federation of Physicians and Surgeons -- or Physicians</p> <p>10 and Dentists. They came into the Cincinnati area to</p> <p>11 recruit physicians to join what they considered a legal</p> <p>12 union. And so all the physicians involved in this case,</p> <p>13 and many of the other practices in the city, joined and</p> <p>14 became members of the federation.</p> <p>15 And so we all thought that we were members of</p> <p>16 the union. And they had their union representatives</p> <p>17 come in here and talk to us about how we can negotiate</p> <p>18 with insurance companies from a legal standpoint based</p> <p>19 on their expertise and utilize them in a legal way based</p> <p>20 on their expertise to help us negotiate better terms for</p> <p>21 our reimbursements.</p> <p>22 Q. And working together as a group with the</p> <p>23 federation, you and these other OB-GYNs in the area</p> <p>24 wrote letters, for example, to the insurance companies</p>	<p>1 MR. ZONIES: I'm reading from the document.</p> <p>2 MR. DIPOLA: Okay.</p> <p>3 BY MR. ZONIES:</p> <p>4 Q. "Just think of the money they will save if</p> <p>5 they keep delaying people until 2004." Is that an email</p> <p>6 that you had written?</p> <p>7 A. I don't recall that.</p> <p>8 Q. Do you deny that that is an email that you</p> <p>9 wrote?</p> <p>10 A. I don't recall that.</p> <p>11 Q. If you look at page 44387, paragraph 76, of</p> <p>12 the complaint that was filed by the Department of</p> <p>13 Justice against you and others.</p> <p>14 A. What was that page, 44,000 --</p> <p>15 Q. 44,387.</p> <p>16 A. 87. Okay.</p> <p>17 Q. Paragraph 76.</p> <p>18 A. 76?</p> <p>19 Q. Yes. Do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. The allegation in paragraph 76 by the</p> <p>22 Department of Justice is, "This combination and</p> <p>23 conspiracy has had the following effects, among others,"</p> <p>24 and then it goes on to say in paragraph B, "Healthcare</p>

19 (Pages 70 to 73)

Michael Karram, M.D.

Page 74	Page 76
<p>1 insurance companies in the Cincinnati area and their</p> <p>2 subscribers have been denied the benefits of free and</p> <p>3 open competition in the purchase of OB-GYN services in</p> <p>4 the Cincinnati area." That was the allegation, correct?</p> <p>5 A. That's what it says, yes.</p> <p>6 Q. It goes on to say, "Self-insured employers and</p> <p>7 their employees have paid significantly higher prices</p> <p>8 for OB-GYN services in the Cincinnati area than they</p> <p>9 would have paid in the absence of this restraint of</p> <p>10 trade." That was the allegation, correct?</p> <p>11 A. That's what it says.</p> <p>12 Q. So, for example, some of the services that you</p> <p>13 would have been providing at the time to your patients</p> <p>14 and for which you would be turning for reimbursement</p> <p>15 from Aetna and Humana would be TVT and TVT-O procedures,</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And these are allegations that through the</p> <p>19 efforts of the federation and you and other physicians</p> <p>20 in the area, that the prices for those procedures were</p> <p>21 artificially enhanced by violating the Sherman Act,</p> <p>22 correct?</p> <p>23 MR. DIPAOLO: Object to form.</p> <p>24 A. No, incorrect. That's not correct.</p>	<p>1 A. Yes.</p> <p>2 Q. Would it be your testimony that you have</p> <p>3 reviewed every single one of these articles either in</p> <p>4 the abstract or in detail?</p> <p>5 MR. DIPAOLO: Object to form.</p> <p>6 A. No.</p> <p>7 Q. This was a list that was provided to you? You</p> <p>8 didn't create this list; is that fair?</p> <p>9 A. Some of the articles, and then some of this I</p> <p>10 did provide, and others were provided to me, and I am</p> <p>11 familiar with quite a few of these in the sense that I</p> <p>12 have read either the articles themselves or abstracts or</p> <p>13 maybe have discussed some at conferences or different</p> <p>14 medical meetings.</p> <p>15 Q. You do cite to some papers in the body of your</p> <p>16 report, correct?</p> <p>17 A. Correct.</p> <p>18 Q. The choices you made on which papers to cite</p> <p>19 in the body of your report, what drove that choice?</p> <p>20 A. The articles that I used to prepare my -- and</p> <p>21 the information that I used to prepare my report.</p> <p>22 Q. Do you somehow consider the ones that you</p> <p>23 cited in the body of your report to be the seminal</p> <p>24 papers on the topics that you cite them for?</p>
Page 75	Page 77
<p>1 Q. You don't think that's what the allegations</p> <p>2 were?</p> <p>3 A. No. I think the allegations were that we were</p> <p>4 trying to get reimbursement similar to other parts of</p> <p>5 the country for the procedures that we were</p> <p>6 participating in.</p> <p>7 Q. You were trying to get paid more?</p> <p>8 A. We were trying to get --</p> <p>9 MR. DIPAOLO: Object to form.</p> <p>10 A. -- reimbursed equally across the board just</p> <p>11 like anybody else in the country.</p> <p>12 Q. Had you been involved in any other civil</p> <p>13 actions of any sort involving the United States?</p> <p>14 A. No.</p> <p>15 Q. Have you ever had your medical license in any</p> <p>16 way revoked or put on hold?</p> <p>17 A. No.</p> <p>18 Q. Could you turn, please, to what I'm handing</p> <p>19 you as Exhibit 4, your reliance materials. Do you have</p> <p>20 that in front of you?</p> <p>21 A. Yes.</p> <p>22 Q. Your reliance materials start with a section</p> <p>23 called "Medical Literature" dated 3/2/2016; is that</p> <p>24 right?</p>	<p>1 MR. DIPAOLO: Object to form.</p> <p>2 A. Seminal meaning?</p> <p>3 Q. The key papers on the topics that you're</p> <p>4 citing them for.</p> <p>5 A. Just in my opinion what I looked at, yes.</p> <p>6 Q. What you would choose to back up your opinions</p> <p>7 effectively?</p> <p>8 A. Some of them, yes.</p> <p>9 Q. Did you cite in your report any papers you</p> <p>10 felt didn't support your opinion but you analyzed why</p> <p>11 they wouldn't be applicable?</p> <p>12 MR. DIPAOLO: Object to form.</p> <p>13 A. No.</p> <p>14 Q. In your report, you only cite those papers</p> <p>15 that support your opinion, correct?</p> <p>16 A. Yes, for the most part, yes.</p> <p>17 Q. If you keep on going, the next section is</p> <p>18 called "Production Materials." Do you see that? It's</p> <p>19 just after the last Zyczynski, Z-y-c-z-y-n-s-k-i.</p> <p>20 A. This (indicating)?</p> <p>21 Q. Yes.</p> <p>22 A. Okay.</p> <p>23 Q. Do you see in the top left corner of that, it</p> <p>24 says "Production Materials"?</p>

20 (Pages 74 to 77)

Michael Karram, M.D.

Page 78	Page 80
<p>1 A. Yes.</p> <p>2 Q. All right. And if you look at that page and</p> <p>3 the next page, this is what I was talking about where it</p> <p>4 says ETH.MESH. Do you see a lot of those ETH.MESH?</p> <p>5 A. Yes.</p> <p>6 Q. These are internal Ethicon documents?</p> <p>7 A. Right.</p> <p>8 Q. These documents -- you've already said that</p> <p>9 you haven't reviewed internal documents, correct?</p> <p>10 MR. DIPAOLO: Object to form.</p> <p>11 A. That's correct, I have not.</p> <p>12 Q. So you haven't reviewed, for example, an</p> <p>13 email -- if you look at the second page at the top,</p> <p>14 "Email from Dan Smith, re: NG TVT-O NDP. Outcomes from</p> <p>15 kickoff meeting with Professor De Leval and</p> <p>16 Dr. Waltregny, ETH.MESH.2293715-6." You wouldn't have</p> <p>17 reviewed that document, correct?</p> <p>18 A. Correct.</p> <p>19 Q. And you're not relying on that document for</p> <p>20 your opinion, correct?</p> <p>21 A. Correct.</p> <p>22 Q. Would the same be said of all of these</p> <p>23 ETH.MESH documents or the documents that say "Email from</p> <p>24 Hinoul," et cetera?</p>	<p>1 A. Yes.</p> <p>2 Q. It sounds to me, just from reading the title,</p> <p>3 that that might be a prof ed piece.</p> <p>4 A. It could be, yes, and if it was, I probably</p> <p>5 saw it in some form.</p> <p>6 Q. At some point --</p> <p>7 A. Yes.</p> <p>8 Q. -- or in particular for working on your</p> <p>9 opinion?</p> <p>10 A. No. Probably in prof ed when I was giving a</p> <p>11 course or something.</p> <p>12 Q. Understood.</p> <p>13 A. Right.</p> <p>14 Q. But even the prof ed ones that might be listed</p> <p>15 on here, you didn't specifically look at those in</p> <p>16 preparation of your report and rely upon those; is that</p> <p>17 fair?</p> <p>18 A. No.</p> <p>19 MR. DIPAOLO: Object to form.</p> <p>20 A. Correct.</p> <p>21 Q. As a matter of fact, have you seen any</p> <p>22 documents where on the bottom right corner of the</p> <p>23 document it says ETH.MESH and there's a number?</p> <p>24 A. No, not that I'm aware of.</p>
Page 79	Page 81
<p>1 MR. DIPAOLO: Object to form; foundation.</p> <p>2 A. Any email or documents, yes, if there's</p> <p>3 something in here that has to do with a prof ed slide, I</p> <p>4 might have looked at. But other than that, no, I'm not</p> <p>5 familiar with any of this.</p> <p>6 Q. So, for example, if you turn to the next page,</p> <p>7 the sixth one down is entitled "Gynemesh PS Slide Deck</p> <p>8 2004," that may be a prof ed piece, for example?</p> <p>9 A. Correct.</p> <p>10 Q. So that's something you may have reviewed?</p> <p>11 A. Or I may have looked at, yes, or seen.</p> <p>12 Q. Do you know if you actually did look at that?</p> <p>13 MR. DIPAOLO: Object to form.</p> <p>14 A. "The Gynecare Gynemesh PS, a new mesh for</p> <p>15 pelvic floor repair," is that what you're looking at</p> <p>16 under "Government Submissions"? I don't know which page</p> <p>17 you're on.</p> <p>18 Q. I'm sorry.</p> <p>19 A. That's all right. That's all right.</p> <p>20 Q. They're not numbered. So if you back up one</p> <p>21 page.</p> <p>22 A. Okay.</p> <p>23 Q. And if you look at the sixth one down, it</p> <p>24 says, "Gynemesh PS Slide Deck 2004." Do you see that?</p>	<p>1 Q. In the preparation of your report, the time</p> <p>2 frame we said was four or five months; is that right?</p> <p>3 A. Maybe more, two to three. February -- well,</p> <p>4 let's see. January, in that range, three months, three</p> <p>5 to four months.</p> <p>6 Q. So maybe December 2014, January 20 --</p> <p>7 A. No, December '15 into January '16, yes.</p> <p>8 Q. So December '15 into January 16, I'd like to</p> <p>9 focus on that time frame.</p> <p>10 A. Okay.</p> <p>11 Q. In that time frame and in preparing your</p> <p>12 report for this case, did you review any patient</p> <p>13 brochures?</p> <p>14 A. No.</p> <p>15 Q. In that time frame and in the preparation of</p> <p>16 your report for this case, did you review any IFUs for</p> <p>17 any of the TVT products?</p> <p>18 A. No.</p> <p>19 Q. In that time frame in the preparation of your</p> <p>20 report, did you review any specific scientific articles?</p> <p>21 MR. DIPAOLO: Object to form; vague.</p> <p>22 A. Yes.</p> <p>23 Q. How would I discern which ones you reviewed?</p> <p>24 Would those be the ones listed in the body of your</p>

21 (Pages 78 to 81)

Michael Karram, M.D.

Page 82	Page 84
<p>1 report?</p> <p>2 A. Some. I looked at the Cochrane review</p> <p>3 articles in there. Those were probably the majority of</p> <p>4 what I looked at.</p> <p>5 Q. When you say you looked at the Cochrane</p> <p>6 review, you cite in your report to the Ogah study from</p> <p>7 2011, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Is there a reason you didn't choose to cite to</p> <p>10 the Ford-Cochrane review from 2015?</p> <p>11 A. No.</p> <p>12 Q. Did you understand that that existed?</p> <p>13 A. Yes.</p> <p>14 Q. Have you reviewed the Nambiar-Cochrane review</p> <p>15 on single-incision slings from 2014?</p> <p>16 MR. DIPAOLA: Object to form.</p> <p>17 A. No.</p> <p>18 Q. Would it be fair to say that the bulk of your</p> <p>19 expert report focuses on the TVT Retropubic device?</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 A. No.</p> <p>22 Q. Would you be surprised that the word</p> <p>23 "obturator" only shows up twice in your report?</p> <p>24 MR. DIPAOLA: Object.</p>	<p>1 Q. It gets loud at my house on Christmas.</p> <p>2 Do you believe there are differences between</p> <p>3 the mesh used in the TVT slings and the mesh that's used</p> <p>4 in the AMS slings?</p> <p>5 A. Yes.</p> <p>6 Q. What do you believe those differences to be?</p> <p>7 A. The laser cut of the slings with Ethicon</p> <p>8 versus the AMS products.</p> <p>9 Q. The AMS products are mechanically cut?</p> <p>10 A. I think so, yes.</p> <p>11 Q. Do you find there is a difference in the</p> <p>12 characteristics between a laser cut mesh and a</p> <p>13 mechanically cut mesh?</p> <p>14 A. Visibly, yes. Clinically, no.</p> <p>15 Q. Is it a decision-making point for you ever</p> <p>16 when you're deciding to use a particular device whether</p> <p>17 it's laser cut or mechanically cut?</p> <p>18 A. No.</p> <p>19 Q. Do you believe that in your hands a laser cut</p> <p>20 mesh is a little stiffer than a mechanically cut mesh?</p> <p>21 MR. DIPAOLA: Object to form.</p> <p>22 A. No.</p> <p>23 Q. Have you ever seen documents that demonstrate</p> <p>24 the different characteristics of mechanically cut mesh</p>
Page 83	Page 85
<p>1 A. No.</p> <p>2 Q. Do you think that your report is focused on</p> <p>3 the TVT Obturator?</p> <p>4 MR. DIPAOLA: Object; asked and answered.</p> <p>5 A. I think it's focused on synthetic slings used</p> <p>6 for stress incontinence.</p> <p>7 Q. Do you believe it's focused on</p> <p>8 Ethicon-manufactured synthetic slings for stress urinary</p> <p>9 incontinence?</p> <p>10 A. Yes.</p> <p>11 Q. When you're making a decision between using an</p> <p>12 Ethicon mesh or an AMS mesh, what drives your decision?</p> <p>13 MR. DIPAOLA: Object to form.</p> <p>14 A. You're talking about slings?</p> <p>15 Q. I'm talking about slings. Thank you.</p> <p>16 A. Okay. Experience, data.</p> <p>17 Q. What do you find to be the differences --</p> <p>18 MR. DIPAOLA: Were you done with your answer?</p> <p>19 Were you done?</p> <p>20 THE WITNESS: Yeah.</p> <p>21 Q. And if I interrupt, please interrupt back.</p> <p>22 A. I will, I will.</p> <p>23 Q. It's the Italian in me.</p> <p>24 A. I understand.</p>	<p>1 and laser cut mesh?</p> <p>2 A. No.</p> <p>3 Q. Have you ever seen Ethicon's internal bench</p> <p>4 testing showing the difference in elasticity between</p> <p>5 laser cut and mechanically cut mesh?</p> <p>6 MR. DIPAOLA: Object to form; asked and</p> <p>7 answered.</p> <p>8 A. No.</p> <p>9 Q. When you use a TVT Obturator product -- do you</p> <p>10 still use TVT Obturators today?</p> <p>11 A. Yes.</p> <p>12 Q. When you use a TVT Obturator product, do you</p> <p>13 specifically request the laser cut version of the TVT-O?</p> <p>14 A. No.</p> <p>15 Q. Do you request a mechanically cut version?</p> <p>16 A. No.</p> <p>17 Q. Do you know which it is that you receive when</p> <p>18 you get a TVT Obturator?</p> <p>19 A. With the Monarc, I do. With the TVT Abbrevio,</p> <p>20 I do.</p> <p>21 Q. What about with --</p> <p>22 A. And with TVT Exact, I do.</p> <p>23 Q. What about with the TVT Obturator?</p> <p>24 A. We don't use the TVT Obturator anymore.</p>

22 (Pages 82 to 85)

Michael Karram, M.D.

<p style="text-align: right;">Page 86</p> <p>1 Q. Okay. I'm sorry. When was the last time you</p> <p>2 used a TVT Obturator?</p> <p>3 A. Probably four or five years ago. When Abbrevio</p> <p>4 came out, I guess, whenever that came out.</p> <p>5 Q. So when Abbrevio came out in 2009 or '10, that</p> <p>6 was the last time you used a TVT Obturator?</p> <p>7 A. Correct.</p> <p>8 Q. The full-length --</p> <p>9 A. The full-length inside-out Ethicon product.</p> <p>10 Q. Is the same true for TVT Retropubic and the</p> <p>11 Exact, that is, that once the Exact came out, you</p> <p>12 stopped use the retropubic device?</p> <p>13 A. Yes.</p> <p>14 Q. Why did you stop use the TVT Obturator when</p> <p>15 the Abbrevio came out?</p> <p>16 MR. DIPAOLO: Object to form.</p> <p>17 A. The Abbrevio data showed the same effect, and</p> <p>18 our data with our patients showed the same effect, or my</p> <p>19 data, and it was in our opinion, or my opinion, less</p> <p>20 groin pain. So with the same effect, less pain, we</p> <p>21 started using the Abbrevio.</p> <p>22 Q. Did you ever implant a TVT Obturator</p> <p>23 full-length sling after you started to use the Abbrevio?</p> <p>24 A. Actually, I have not.</p>	<p style="text-align: right;">Page 88</p> <p>1 five minutes for me. Thank you.</p> <p>2 MR. ZONIES: I need to take another break.</p> <p>3 (Short recess taken.)</p> <p>4 BY MR. ZONIES:</p> <p>5 Q. Doctor, before the break, we were discussing</p> <p>6 your use of various obturator slings. Do you recall</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. So I want to be sure that I understand your</p> <p>10 current practice. If a patient presents to you and you</p> <p>11 believe it's best that they get an obturator sling</p> <p>12 implanted, it sounds to me like you choose either the</p> <p>13 TVT Abbrevio or the Monarc; is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. And the Monarc is the full-length sling that's</p> <p>16 made by AMS, correct?</p> <p>17 A. Correct.</p> <p>18 Q. You do not use the TVT Obturator device in</p> <p>19 your practice, correct?</p> <p>20 A. Now.</p> <p>21 Q. Now.</p> <p>22 A. Yeah, correct.</p> <p>23 Q. And you haven't used that since TVT Abbrevio</p> <p>24 came onto the market, correct?</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. Can you think of any particular reason why a</p> <p>2 patient, a particular patient, would call for a TVT</p> <p>3 Obturator full-length sling instead of an Abbrevio?</p> <p>4 A. Yes.</p> <p>5 Q. What is that situation?</p> <p>6 A. Somebody who has lower leak point pressures,</p> <p>7 or somebody who has more hypermobility than you would</p> <p>8 like with an Abbrevio.</p> <p>9 Q. What is the difference between the Abbrevio and</p> <p>10 the TVT Obturator that you think makes one better than</p> <p>11 the other in those situations?</p> <p>12 MR. DIPAOLO: Object to form.</p> <p>13 A. The Abbrevio is the pain, I think. There's</p> <p>14 less pain in the groin.</p> <p>15 Q. But you also said that there might be a reason</p> <p>16 to use an obturator.</p> <p>17 A. A long -- yes.</p> <p>18 Q. If --</p> <p>19 A. I guess -- let me clarify it. I still use</p> <p>20 long obturators; but in that situation, I use a Monarc</p> <p>21 outside-in AMS product. So I'm still using the long</p> <p>22 one. I'm not just using Abbrevio as a TOT. Does that</p> <p>23 make sense?</p> <p>24 Q. It does. That actually clarifies the last</p>	<p style="text-align: right;">Page 89</p> <p>1 A. Correct.</p> <p>2 Q. One of the reasons that you chose to switch</p> <p>3 over to the TVT Abbrevio is your belief that it had</p> <p>4 similar outcomes as the TVT Obturator, full length, from</p> <p>5 Ethicon but exhibited less groin and thigh pain,</p> <p>6 correct?</p> <p>7 A. Correct.</p> <p>8 Q. So, for you, that is the chosen TVT device,</p> <p>9 Ethicon device, to use in the obturator approach,</p> <p>10 correct?</p> <p>11 MR. DIPAOLO: Object to form.</p> <p>12 A. To a certain extent. When Abbrevio came out, I</p> <p>13 thought, and I was under the impression, that they</p> <p>14 weren't going to market the TVT-O anymore. And, in</p> <p>15 fact, I just found out last week from some doctors in</p> <p>16 Dayton that they still do. But at our hospital, we</p> <p>17 didn't stock it. Once Abbrevio came out, they stopped</p> <p>18 stocking TVT-O, and I just assumed that TVT-O was off</p> <p>19 the market, but apparently it isn't. So now if we can</p> <p>20 get it, I will get it, and I will probably start using</p> <p>21 it again.</p> <p>22 Q. In your current practice, when you want to use</p> <p>23 a full-length sling, you choose the AMS product,</p> <p>24 correct?</p>

23 (Pages 86 to 89)

Michael Karram, M.D.

<p style="text-align: right;">Page 90</p> <p>1 A. Because that's the only one we have.</p> <p>2 Q. The only full-length obturator sling that you</p> <p>3 have available?</p> <p>4 A. At our hospital, yes.</p> <p>5 Q. If you do decide to get the TVT Obturator into</p> <p>6 your hospital and you can manage to do so, will you</p> <p>7 specifically request the laser cut version of the TVT</p> <p>8 Obturator?</p> <p>9 MR. DIPAOLA: Object to form.</p> <p>10 A. Yes.</p> <p>11 Q. What is it that you like about the laser cut</p> <p>12 of the mesh as compared to the mechanically cut mesh?</p> <p>13 A. Visibly it looks cleaner when you're putting</p> <p>14 it in the space. It is, in my opinion, easier to</p> <p>15 tension because of the way the edges are cut versus a</p> <p>16 mechanical cut. Those are probably the two biggest</p> <p>17 reasons.</p> <p>18 Q. When you were using mechanically cut TVT</p> <p>19 devices, you noticed that the edges were sometimes</p> <p>20 frayed, for example?</p> <p>21 MR. DIPAOLA: Object to form.</p> <p>22 A. I wouldn't say frayed. They looked different</p> <p>23 than a laser cut.</p> <p>24 Q. They were -- I've heard it described sometimes</p>	<p style="text-align: right;">Page 92</p> <p>1 TVT Retropubic; is that correct?</p> <p>2 A. No.</p> <p>3 MR. DIPAOLA: Object to form.</p> <p>4 A. No, TVT Exact is not a shorter sling.</p> <p>5 Q. When you started to use the TVT Exact, you</p> <p>6 stopped using the TVT Retropubic; is that correct?</p> <p>7 A. The original TVT Retropubic, it was just the</p> <p>8 introduction device is different, and the introducer is</p> <p>9 different.</p> <p>10 Q. I apologize.</p> <p>11 A. Okay.</p> <p>12 Q. I'm mixing up my Abbrevos and all --</p> <p>13 A. That's okay.</p> <p>14 Q. When you started to use the TVT Exact, did you</p> <p>15 completely stop using the TVT Retropubic, the original?</p> <p>16 A. Yes.</p> <p>17 Q. And assuming the TVT Retropubic original is</p> <p>18 still available on the market, is it something that you</p> <p>19 would choose to use today, or is it not available in</p> <p>20 your --</p> <p>21 A. It is still available --</p> <p>22 MR. DIPAOLA: Object to form.</p> <p>23 A. -- but I don't choose to use it anymore.</p> <p>24 Q. What was the primary driver for you to stop</p>
<p style="text-align: right;">Page 91</p> <p>1 as sharper. Is that fair?</p> <p>2 MR. DIPAOLA: Object to form.</p> <p>3 A. I wouldn't say sharper. I would just say it</p> <p>4 looks physically different.</p> <p>5 Q. Did you ever experience particle loss, blue</p> <p>6 pieces of polypropylene in the packaging or in the body</p> <p>7 as you were implanting a device?</p> <p>8 A. I never experienced that.</p> <p>9 Q. You didn't see a difference between the</p> <p>10 mechanically cut mesh and the particle loss as compared</p> <p>11 to the laser cut mesh?</p> <p>12 MR. DIPAOLA: Object to form.</p> <p>13 A. No.</p> <p>14 Q. You've never seen any internal Ethicon</p> <p>15 documents discussing those differences between the laser</p> <p>16 cut mesh and the mechanically cut mesh, correct?</p> <p>17 MR. DIPAOLA: Asked and answered.</p> <p>18 A. I have not.</p> <p>19 Q. With regard to the TVT Retropubic device, I</p> <p>20 believe you testified that you used the TVT Retropubic</p> <p>21 device until the TVT Exact came to market, correct?</p> <p>22 A. Correct.</p> <p>23 Q. Then when the TVT Exact came to market, which</p> <p>24 is a shorter sling, you stopped using the full-length</p>	<p style="text-align: right;">Page 93</p> <p>1 using the TVT Retropubic?</p> <p>2 A. The original TVT?</p> <p>3 MR. DIPAOLA: Object to form.</p> <p>4 A. Because TVT Exact is a TVT Retropubic.</p> <p>5 Q. We call them TVT-R and TVT-E.</p> <p>6 A. Okay. All right.</p> <p>7 Q. So I'll ask it cleaner.</p> <p>8 A. Okay. Go ahead.</p> <p>9 Q. What was the primary driver for you to stop</p> <p>10 using the original TVT Retropubic and move to the TVT</p> <p>11 Exact device?</p> <p>12 A. The tactile sensation with the new device was</p> <p>13 much better. We also have a fellowship program where</p> <p>14 we're teaching fellows and residents how to do these</p> <p>15 types of procedures. And from a teaching standpoint, it</p> <p>16 was a much easier procedure to teach because of the</p> <p>17 tactile sensation that you feel as you're going behind</p> <p>18 the retropubic bone. And in my experience, I saw less</p> <p>19 bladder injuries at the time of insertion, but that's</p> <p>20 just my experience, especially teaching residents and</p> <p>21 fellows. So those were the reasons why we went through</p> <p>22 the transition to TVT-E.</p> <p>23 Q. So it sounds like the primary drivers for</p> <p>24 switching to the TVT-E were the ease of use during the</p>

24 (Pages 90 to 93)

Michael Karram, M.D.

Page 94	Page 96
<p>1 operative procedure and the fewer complications; in 2 particular, bladder perforations, correct? 3 A. Correct. 4 Q. And the TVT Retropubic, the original one, is 5 still available for you to use; however, you haven't 6 used it since the introduction of the TVT Exact? 7 A. That's correct. 8 Q. In your expert report, there's a section 9 shortly after that starts with "Results and References." 10 Do you see that? 11 A. I do. 12 Q. This goes on for five and a half, six pages, 13 correct? 14 A. Correct. 15 Q. When you wrote this section of your report 16 entitled "Results and References," were these -- as we 17 discussed earlier, were these the main reference 18 materials that you rely upon in offering your opinions 19 in this case? 20 MR. DIPAOLA: Object to form. 21 A. They're the ones that I listed, but I rely on 22 all my background teachings and what I've learned in my 23 experience throughout my career, and a lot of these are 24 similar studies that regurgitate the same thing that we</p>	<p>1 and I thought that the information there was very 2 relevant and prevalent. 3 Q. I've got the study. Let me go ahead and pull 4 it out. 5 --- 6 ARTICLE ENTITLED, "RETROPUBIC 7 VERSUS TRANSOBTURATOR MIDURETHRAL 8 SLINGS FOR STRESS INCONTINENCE" WAS 9 MARKED AS EXHIBIT NO. 8. 10 --- 11 Q. Doctor, I'm marking Exhibit 8, which is the 12 study in the New England Journal of Medicine entitled 13 "Retropubic Versus Transobturator Midurethral Slings for 14 Stress Incontinence" with the lead author being Richter, 15 R-i-c-h-t-e-r, and it is commonly known as the TOMUS 16 study, T-O-M-U-S; is that right? 17 A. That's correct. 18 Q. You felt this paper was reflective of your 19 opinions in this case, and you relied upon it, correct? 20 A. Yes. 21 Q. The paper has a finding in the conclusions 22 that "The rates of subjectively assessed success were 23 similar between groups but did not meet the criteria for 24 equivalence." Is that correct?</p>
Page 95	Page 97
<p>1 found in previous studies. 2 So I can say these are probably the ones that 3 I utilized the most, but I also, you know, rely on my 4 textbooks, my past experience, all the journal articles 5 that I've read, and I get about six journals in this 6 field, and so you're always reading abstracts and 7 reading things that catch your eye, yes. 8 Q. But when writing your report, these were the 9 ones that you felt comfortable as capturing your 10 opinions essentially? 11 MR. DIPAOLA: Object to form. 12 A. These were the majority of them, yes. 13 Q. One of the first studies you talk about is the 14 Cochrane study that we discussed, the Ogah study, 15 correct? 16 A. Correct. 17 Q. And you go on to discuss the TOMUS, T-O-M-U-S, 18 study. Richter, R-i-c-h-t-e-r, is the lead author on 19 that study, correct? 20 A. Right. 21 Q. Why did you choose to discuss the TOMUS study? 22 A. That was a study that was supported by the 23 AUGS federation and their group, and it was a very 24 well-designed study that looked at midurethral slings,</p>	<p>1 A. That's what it says, yes. 2 Q. So in this paper, if you look in the "Results" 3 section, it states that -- in the "Abstract." Sorry. 4 It states that "The rates of subjectively assessed 5 success were 62.2 percent and 55.8 percent, 6 respectively," the first being retropubic and the second 7 being transobturator, correct? 8 A. Correct. 9 Q. So the failure rate for the transobtutors in 10 this study was roughly 44 percent, correct? 11 MR. DIPAOLA: Object to form. 12 A. Yes. 13 Q. Do you believe that correctly reflects the 14 failure rates for TVT Obturators? 15 MR. DIPAOLA: Object to form. 16 A. Not in my hands, no. 17 Q. But you chose to cite to this study, correct? 18 A. I did cite this study, correct. 19 Q. And this study also stands for the proposition 20 that TVT Retropubic has a higher success rate than does 21 TVT Obturator, correct? 22 MR. DIPAOLA: Object to form. 23 A. I don't -- did they -- I don't think that was 24 clinically significant.</p>

25 (Pages 94 to 97)

Michael Karram, M.D.

Page 98	Page 100
<p>1 Q. It failed to show equivalency, correct?</p> <p>2 A. Yeah, but that doesn't necessarily mean that</p> <p>3 it's clinically significant.</p> <p>4 Q. What do you mean by that?</p> <p>5 A. Well, what were their confidence intervals and</p> <p>6 did their confidence intervals show a P value for a</p> <p>7 result that was clinically significant?</p> <p>8 Q. Do you see in the "Methods" section, the last</p> <p>9 sentence, "The predetermined equivalence margin was plus</p> <p>10 or minus 12 percentage points"?</p> <p>11 A. Okay.</p> <p>12 Q. Do you see that?</p> <p>13 A. Yes, I do.</p> <p>14 Q. So do you know what an equivalency study is?</p> <p>15 A. I don't know what this exactly means, that</p> <p>16 they were a predetermined equivalence margin. It's a</p> <p>17 statistical term that I'm not familiar with.</p> <p>18 Q. Okay. Do you know what a non-inferiority</p> <p>19 study is?</p> <p>20 A. Yes.</p> <p>21 Q. If you turn to page 8 of the study, it has an</p> <p>22 adverse events chart.</p> <p>23 A. Yes.</p> <p>24 Q. If you look at the adverse event chart for the</p>	<p>1 Q. And you talked about one other one. Did you</p> <p>2 say extrusion?</p> <p>3 A. Extrusion and exposure, I think, are used</p> <p>4 simultaneously. Erosion, I think most people would say</p> <p>5 is into a viscus.</p> <p>6 Q. And what about a perforation?</p> <p>7 A. That's different.</p> <p>8 Q. How is a perforation different?</p> <p>9 A. You don't perforate with a mesh. You</p> <p>10 perforate with an introducer.</p> <p>11 Q. So further down in this chart they talk about</p> <p>12 perforations. Those would be from the trocars?</p> <p>13 A. Correct, the introducers.</p> <p>14 Q. On the next page of your expert report is the</p> <p>15 first, I think, in a series of photographs of a computer</p> <p>16 screen, correct?</p> <p>17 A. Correct.</p> <p>18 Q. How was that photograph generated?</p> <p>19 A. My phone.</p> <p>20 Q. You took a picture of your computer screen</p> <p>21 with your phone?</p> <p>22 A. Yes.</p> <p>23 Q. That is old school.</p> <p>24 The study that you present here is only TVT</p>
Page 99	Page 101
<p>1 retropubic sling, it has nine events of a mesh exposure</p> <p>2 in eight patients. Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. For 2.7 percent of the patients having an</p> <p>5 exposure. Is that consistent with your practice?</p> <p>6 MR. DIPAOLA: Object to form.</p> <p>7 A. Okay. So let me see. No. I have a lower</p> <p>8 rate of mesh exposure in my practice.</p> <p>9 Q. And then it also has mesh erosion underneath</p> <p>10 that?</p> <p>11 A. Um-hmm.</p> <p>12 Q. Yes?</p> <p>13 A. Yes. Sorry.</p> <p>14 Q. What's the difference between exposure and</p> <p>15 erosion?</p> <p>16 A. I think it depends on what surgeon you're</p> <p>17 talking to or what group you're talking to. In my</p> <p>18 opinion, an erosion is an erosion into a viscus, which</p> <p>19 would be the bladder or the bowel. An extrusion would</p> <p>20 be into the vagina. That's how I describe the two.</p> <p>21 So I'm not real sure what they were referring</p> <p>22 to as an erosion. Most likely, I would think they were</p> <p>23 referring to the same thing since they have both erosion</p> <p>24 and exposure.</p>	<p>1 Retropubic, correct?</p> <p>2 A. That is correct.</p> <p>3 Q. On the next page, you have rates of surgical</p> <p>4 cure. Can you describe for me what that slide shows?</p> <p>5 A. Yes. This is a slide that was used in, again,</p> <p>6 a teaching program showing the different historical</p> <p>7 rates, average rates, of what we would consider cured or</p> <p>8 subjective cure for the different procedures that have</p> <p>9 been used historically. Anterior colporrhaphy, average</p> <p>10 was 60 percent. Retropubic colposuspension would either</p> <p>11 be a Burch or an MMK. That was 84 percent. And needle</p> <p>12 urethropexy would be like a Stamey or a Pereyra,</p> <p>13 88 percent. And then you have the synthetic slings,</p> <p>14 which would be TVT and TVT-O or TOT Obturator, which</p> <p>15 would be 88 percent. And then the last one would be a</p> <p>16 pubovaginal fascial sling, which would be 81 percent.</p> <p>17 Q. Have you performed all of these at one time in</p> <p>18 your career?</p> <p>19 A. Yes. Well, actually, no. I've performed</p> <p>20 anterior colporrhaphy, but I did not perform it for the</p> <p>21 treatment of stress incontinence.</p> <p>22 Q. What did you perform that for?</p> <p>23 A. For an anterior cystocele.</p> <p>24 Q. You've said that you've done 2,000 slings or</p>

26 (Pages 98 to 101)

Michael Karram, M.D.

Page 102	Page 104
<p>1 so.</p> <p>2 A. Approximately, yes.</p> <p>3 Q. Do you also do prolapse repairs?</p> <p>4 A. Yes.</p> <p>5 MR. DIPAOLA: Object to form.</p> <p>6 Q. Do you use synthetic meshes in your prolapse</p> <p>7 repairs?</p> <p>8 MR. DIPAOLA: Object to form; beyond the</p> <p>9 scope.</p> <p>10 A. I have, yes.</p> <p>11 Q. How many POP procedures with a synthetic mesh</p> <p>12 do you think you've done over your career?</p> <p>13 MR. DIPAOLA: Same objection.</p> <p>14 A. 300, 350.</p> <p>15 Q. Not nearly as many as slings?</p> <p>16 A. No.</p> <p>17 MR. DIPAOLA: Object.</p> <p>18 A. No.</p> <p>19 Q. The presentation that we're looking at that is</p> <p>20 a photograph using your phone of your computer screen,</p> <p>21 that presentation, I presume, resides on your computer,</p> <p>22 correct?</p> <p>23 A. Parts of it, yes.</p> <p>24 Q. So that's something that, if I requested it,</p>	<p>1 A. Yes.</p> <p>2 Q. This is the 2002 Hilton. Were there later</p> <p>3 Ward and Hilton studies of this same population?</p> <p>4 A. I'm not aware of them.</p> <p>5 Q. And this is, because it's 2002, limited to the</p> <p>6 TVT Retropubic, correct?</p> <p>7 A. Correct.</p> <p>8 Q. There's nothing in this study nor in the Kuuva</p> <p>9 and Nilsson study we were looking at about the TVT</p> <p>10 Obturator?</p> <p>11 A. That's correct.</p> <p>12 Q. And you would agree with your own slide that</p> <p>13 you're presenting here that bladder injury is more</p> <p>14 common with the TVT than with the Burch, correct?</p> <p>15 MR. DIPAOLA: Object to form.</p> <p>16 A. Repeat that question.</p> <p>17 Q. Sure. The slide we were just looking at from</p> <p>18 Ward and Hilton says -- the quote you're putting in this</p> <p>19 slide is "Bladder injury is more common with TVT than</p> <p>20 Burch," correct?</p> <p>21 A. That's an interesting question. I guess the</p> <p>22 question is, with a TVT, you get the bladder injury from</p> <p>23 the introducer. During a Burch procedure, we always</p> <p>24 injure the bladder. So I'm having a hard time</p>
Page 103	Page 105
<p>1 we could get a drive with your presentation on it?</p> <p>2 MR. DIPAOLA: Object to form. We'll take it</p> <p>3 under advisement should the request come.</p> <p>4 A. It wasn't my presentation, but it is a</p> <p>5 presentation on my computer, yes.</p> <p>6 Q. You told me whose presentation this was.</p> <p>7 A. Mark Walters.</p> <p>8 Q. Okay. Is this a presentation he typically</p> <p>9 gives with your brother?</p> <p>10 A. Not necessarily.</p> <p>11 Q. In addition to this presentation, do you have</p> <p>12 other presentations that you've created and presented on</p> <p>13 your computer as well?</p> <p>14 MR. DIPAOLA: Object to form.</p> <p>15 A. Or other presentations that other doctors have</p> <p>16 presented, yes.</p> <p>17 Q. And those are available on your computer, or</p> <p>18 you could pull those up and shoot a photo with your</p> <p>19 phone as well?</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 A. Probably.</p> <p>22 Q. On the next page, you have a screenshot of the</p> <p>23 Ward and Hilton study, 2002, comparing Burch to TVT,</p> <p>24 correct?</p>	<p>1 distinguishing the two. And the reason we do that is</p> <p>2 because when we do Burch, we use a permanent suture, and</p> <p>3 so before we close the abdomen, we have to open up the</p> <p>4 bladder so that we can see if the sutures are in the</p> <p>5 bladder or not.</p> <p>6 So at that point, we open up the bladder, so</p> <p>7 that would theoretically be a bladder injury. Check to</p> <p>8 make sure the sutures are not in the bladder, put the</p> <p>9 suprapubic catheter in, close the bladder, and that</p> <p>10 would be the Burch.</p> <p>11 So theoretically if you say that's a bladder</p> <p>12 injury, then we injure the bladder every time we do a</p> <p>13 Burch. But I think they are referring to the actual</p> <p>14 technique of the TVT versus the technique of the Burch.</p> <p>15 Q. So if you wanted to make this more clear in</p> <p>16 your report, would it be fair to say -- add the phrase</p> <p>17 "inadvertent bladder injury"?</p> <p>18 A. Correct.</p> <p>19 Q. Gotcha. So just to be sure I've got it then,</p> <p>20 you would take the last bullet point and say inadvertent</p> <p>21 bladder injury is more common with TVT than with Burch?</p> <p>22 A. That's correct.</p> <p>23 Q. On the next page, you have a slide that's</p> <p>24 entitled "TVT Long-Term Follow-up Data." Do you see</p>

27 (Pages 102 to 105)

Michael Karram, M.D.

Page 106	Page 108
<p>1 that?</p> <p>2 A. Yes.</p> <p>3 Q. And, again, this is citing five studies.</p> <p>4 Those are all only about the TVT Retropubic, not the TVT</p> <p>5 Obturator, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. In the Olson study, the last Olson, with one</p> <p>8 S, do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. The last one on the slide --</p> <p>11 A. Yes.</p> <p>12 Q. -- has various percentages; dry, 77 percent,</p> <p>13 improved, 18 percent; failed, 15 percent. That adds up</p> <p>14 to 110 percent. Do you have a sense of where the</p> <p>15 mistake is there?</p> <p>16 A. No, I don't.</p> <p>17 Q. You would agree that that appears to be an</p> <p>18 error?</p> <p>19 A. Unless -- it depends on how they defined dry,</p> <p>20 improved and failed.</p> <p>21 Q. Whether or not they overlapped?</p> <p>22 A. Correct.</p> <p>23 Q. Then for the Rezapour study -- let me ask</p> <p>24 this. This is a presentation that you've given to other</p>	<p>1 their legal department.</p> <p>2 Q. And if we turn back to your report, Doctor,</p> <p>3 the chart we were just looking at, if you look just</p> <p>4 above Olson, there's Rezapour, R-e-z-a-p-o-u-r. Do you</p> <p>5 see that?</p> <p>6 A. Yes.</p> <p>7 Q. If you add those percentages up, it adds up to</p> <p>8 94 percent. Do you know why that is?</p> <p>9 A. Again, I would have to look at how they</p> <p>10 distinguished, and maybe there were some overlaps.</p> <p>11 ---</p> <p>12 ARTICLE ENTITLED, "TENSION-FREE</p> <p>13 VAGINAL TAPE (TVT) IN WOMEN WITH</p> <p>14 RECURRENT STRESS URINARY</p> <p>15 INCONTINENCE - A LONG-TERM FOLLOW</p> <p>16 UP" WAS MARKED AS EXHIBIT NO. 9.</p> <p>17 ---</p> <p>18 Q. I'm going to hand you Exhibit 9, which is the</p> <p>19 Rezapour study.</p> <p>20 A. Okay.</p> <p>21 Q. And if you look just in the "Abstract"</p> <p>22 section, the last sentence of the first paragraph</p> <p>23 starting with the word "According," are you with me?</p> <p>24 A. The last --</p>
Page 107	Page 109
<p>1 physicians, correct?</p> <p>2 A. I've used this slide, yes.</p> <p>3 Q. Have you used this slide in professional</p> <p>4 education?</p> <p>5 A. I don't think I have, because all the</p> <p>6 professional education slides were given to us by the</p> <p>7 company, and we had to use their slide decks, and I'm</p> <p>8 not real sure if this was in their slide deck.</p> <p>9 Q. That's a good point, Doctor. So when you were</p> <p>10 acting as a consultant for Ethicon and speaking on</p> <p>11 Ethicon's behalf, the materials that you presented were</p> <p>12 created and provided to you by Ethicon, correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Were you permitted to make changes to those</p> <p>15 materials?</p> <p>16 MR. DIPOLA: Object to form.</p> <p>17 A. If we did, it had to go through their legal</p> <p>18 department, and they had to approve it before, and I'm</p> <p>19 not aware of ever making any changes.</p> <p>20 Q. So you weren't permitted to make any changes</p> <p>21 to the materials provided to you by Ethicon --</p> <p>22 MR. DIPOLA: Object to form; misstates.</p> <p>23 Q. -- is that correct?</p> <p>24 A. We couldn't change it unless we went through</p>	<p>1 Q. "Abstract."</p> <p>2 A. The last sentence in the paragraph?</p> <p>3 Q. In the first paragraph, yeah.</p> <p>4 A. Oh, okay. Yes, yes.</p> <p>5 Q. If you look at the Rezapour study, Exhibit 9,</p> <p>6 Doctor, it says, "According to the protocol, 28 patients</p> <p>7 (82%) were cured, 3 (9%) were significantly improved,</p> <p>8 and the operation failed in 3 cases (9%)." So your</p> <p>9 slide that you put in your expert report undervalues or</p> <p>10 understates the failure rate by -- it should be</p> <p>11 9 percent, not 3 percent, correct?</p> <p>12 A. Correct.</p> <p>13 Q. So that slide has, it appears, two errors in</p> <p>14 it, correct?</p> <p>15 A. Yes, depending on the definition, and it</p> <p>16 should also be that this study was a study on TVT on</p> <p>17 women with recurrent stress incontinence, not the</p> <p>18 primary procedure; whereas, the other studies were</p> <p>19 primary procedures. They weren't done on recurrent, to</p> <p>20 my knowledge. They were follow-ups on all the primary</p> <p>21 procedures.</p> <p>22 Q. So that's another change you'd want to make on</p> <p>23 that slide, is to make that notation?</p> <p>24 A. I would, yes.</p>

28 (Pages 106 to 109)

Michael Karram, M.D.

Page 110	Page 112
<p>1 Q. The next slide is Ulmsten's seminal study from</p> <p>2 1999, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Did you create this bar chart?</p> <p>5 A. No.</p> <p>6 Q. So this bar chart shows -- it appears to me</p> <p>7 that this bar chart shows that there is an increase in</p> <p>8 the number of women who were cured between 12 months and</p> <p>9 24 to 36 months, correct?</p> <p>10 A. That's correct.</p> <p>11 ---</p> <p>12 ARTICLE ENTITLED, "A THREE-YEAR</p> <p>13 FOLLOW UP OF TENSION FREE VAGINAL</p> <p>14 TAPE FOR SURGICAL TREATMENT OF</p> <p>15 FEMALE STRESS URINARY INCONTINENCE"</p> <p>16 WAS MARKED AS EXHIBIT NO. 10.</p> <p>17 ---</p> <p>18 Q. I'm going to hand you the Ulmsten study,</p> <p>19 Exhibit 10. I'm handing that to you now, Doctor.</p> <p>20 You'll see Exhibit 10, Doctor, is Ulmsten's 1999 study</p> <p>21 entitled, "A three-year follow up of tension-free</p> <p>22 vaginal tape for surgical treatment of female stress</p> <p>23 urinary incontinence," correct?</p> <p>24 A. Correct.</p>	<p>1 A. It was probably in a different presentation</p> <p>2 but within the same format of teaching.</p> <p>3 Q. That was my next question. Do you know if</p> <p>4 this slide was used during a professional education?</p> <p>5 A. No.</p> <p>6 Q. No, you don't know, or no --</p> <p>7 A. No, I don't know.</p> <p>8 Q. Okay. And this slide, it appears, would also</p> <p>9 be available on your computer; is that fair?</p> <p>10 A. Yes.</p> <p>11 Q. And if I needed to get a hold of it, I can ask</p> <p>12 your counsel and they can provide that to me, correct?</p> <p>13 A. Correct.</p> <p>14 Q. So you would agree --</p> <p>15 A. Actually, I think you can get it anywhere. It</p> <p>16 was used in an AUGS teaching, and they put out a whole</p> <p>17 teaching manual of every lecture that was given. So all</p> <p>18 the lectures are in it.</p> <p>19 Q. Did you create this slide?</p> <p>20 A. No.</p> <p>21 Q. But you think it was a slide that was</p> <p>22 presented at AUGS by someone?</p> <p>23 A. At one of the AUGS teaching programs, yes.</p> <p>24 Q. And if that slide, indeed, reflects what it</p>
Page 111	Page 113
<p>1 Q. If you take a minute and turn to the fifth</p> <p>2 page, it's page 349 of the study. Are you with me?</p> <p>3 A. I'm getting there. Yes.</p> <p>4 Q. If you look at Figure 4 on page 349, it</p> <p>5 appears to me to be the same data and the same layout as</p> <p>6 in your expert report, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And you'd agree with me that at 12 months as</p> <p>9 compared to the 24 to 36 months in the Ulmsten paper</p> <p>10 itself, that it's actually the same number of women who</p> <p>11 were cured, correct?</p> <p>12 A. Correct.</p> <p>13 Q. There's not an increase as is reflected in</p> <p>14 your expert report, correct?</p> <p>15 A. I'm not real sure that reflects that. I think</p> <p>16 it's the -- I mean, it looks like that, but it might</p> <p>17 just be the way that -- that was not intentional, I</p> <p>18 guess I'm saying. My understanding is they were the</p> <p>19 same between 12 and 24, just like it is here. So this</p> <p>20 could be the way the slide was recreated. And I didn't</p> <p>21 create this slide.</p> <p>22 Q. Understood. Is this slide also part of the</p> <p>23 same presentation that was reflected in the photographs</p> <p>24 that you took of your computer?</p>	<p>1 looks like it reflects, which is an increase in cure</p> <p>2 between months 12 and 24 to 36, it's incorrect?</p> <p>3 MR. DIPAOLO: Object to form.</p> <p>4 A. If this slide was meant to be the slide in the</p> <p>5 original paper, yes.</p> <p>6 Q. Yes, it's incorrect?</p> <p>7 A. Yes, it's incorrect.</p> <p>8 Q. And you would want to correct that in your</p> <p>9 report, correct?</p> <p>10 MR. DIPAOLO: Object to form; assumes facts</p> <p>11 not in evidence.</p> <p>12 A. Yes.</p> <p>13 (Short recess taken.)</p> <p>14 BY MR. ZONIES:</p> <p>15 Q. Doctor, under the Ulmsten diagram, the next</p> <p>16 section of your report is entitled "Company Training,"</p> <p>17 correct?</p> <p>18 A. Correct.</p> <p>19 Q. In this section, you have a statement that</p> <p>20 starts -- the last phrase on this page saying, "It is</p> <p>21 well-known by all pelvic floor surgeons." Do you see</p> <p>22 that?</p> <p>23 A. Yes.</p> <p>24 Q. You don't actually know that, right, that it's</p>

29 (Pages 110 to 113)

Michael Karram, M.D.

Page 114	Page 116
<p>1 well-known by all pelvic floor surgeons, correct?</p> <p>2 MR. DIPOLA: Object to form.</p> <p>3 A. Well, I have never spoken personally with all</p> <p>4 pelvic surgeons, but I have worked with and trained a</p> <p>5 vast number of pelvic surgeons, and they are aware of</p> <p>6 certain things.</p> <p>7 Q. So would it be more accurate, for example, to</p> <p>8 say, "Of the pelvic surgeons I've worked with, it's my</p> <p>9 belief that ..." blank?</p> <p>10 A. No. I would say of all pelvic surgeons that</p> <p>11 are trained in pelvic surgery and have experience in</p> <p>12 pelvic surgery, it would be my belief that they would</p> <p>13 know whatever we're going to talk about.</p> <p>14 Q. But you don't have any personal knowledge?</p> <p>15 You haven't spoken to all pelvic surgeons, correct?</p> <p>16 MR. DIPOLA: Object to form.</p> <p>17 A. No, I have not.</p> <p>18 Q. You go on to say that, "Any surgery for stress</p> <p>19 urinary incontinence or pelvic organ prolapse, with or</p> <p>20 without the use of mesh, can potentially cause</p> <p>21 complications that can be temporary or permanent,"</p> <p>22 correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you then list certain complications,</p>	<p>1 MR. ZONIES: I'll move to strike that as</p> <p>2 nonresponsive.</p> <p>3 A. You are answering your question that I should</p> <p>4 have answered.</p> <p>5 Q. Right. So my question is, with what you have</p> <p>6 written --</p> <p>7 A. Correct.</p> <p>8 Q. -- is it true that surgery for stress urinary</p> <p>9 incontinence with the use of mesh can potentially cause</p> <p>10 permanent pelvic pain?</p> <p>11 MR. DIPOLA: Object; mischaracterizes.</p> <p>12 A. No, that's not what I'm saying.</p> <p>13 Q. Is it true, Doctor, that what you're saying</p> <p>14 here is that surgery for stress urinary incontinence</p> <p>15 with or without mesh can cause permanent pelvic pain?</p> <p>16 A. Correct.</p> <p>17 Q. And, therefore, as a subset of that, isn't it</p> <p>18 also true that surgery for stress urinary incontinence</p> <p>19 with the use of mesh can cause permanent pelvic pain?</p> <p>20 MR. DIPOLA: Same objection.</p> <p>21 A. Or without the use of mesh as well, as a</p> <p>22 subset, yes.</p> <p>23 Q. Both of those subsets are true, correct?</p> <p>24 A. Correct.</p>
Page 115	Page 117
<p>1 correct?</p> <p>2 A. Correct.</p> <p>3 Q. So if I'm reading my disjunctives correctly,</p> <p>4 if that's the right word, my "ors" correctly, that</p> <p>5 sentence could be read as "Any surgery for stress</p> <p>6 urinary incontinence or pelvic organ prolapse with the</p> <p>7 use of mesh can potentially cause complications that</p> <p>8 could be permanent," correct?</p> <p>9 MR. DIPOLA: Object to form;</p> <p>10 mischaracterizes.</p> <p>11 A. Correct.</p> <p>12 Q. And included among those complications that</p> <p>13 with the use of mesh can be permanent, you list pelvic</p> <p>14 pain, correct?</p> <p>15 A. Correct.</p> <p>16 Q. So, in other words, a surgery for stress</p> <p>17 urinary incontinence with the use of mesh can cause</p> <p>18 permanent pelvic pain, correct?</p> <p>19 MR. DIPOLA: Object to form.</p> <p>20 A. And surgery for stress urinary incontinence</p> <p>21 without mesh can cause pelvic pain permanent. That's</p> <p>22 what I'm saying, yes.</p> <p>23 Q. Right.</p> <p>24 A. Correct.</p>	<p>1 Q. So I'll ask it this way. Is it true, Doctor,</p> <p>2 that in your expert opinion, surgery for stress urinary</p> <p>3 incontinence without the use of mesh can potentially</p> <p>4 cause permanent pelvic pain?</p> <p>5 A. Yes.</p> <p>6 Q. Is it also true that surgery for stress</p> <p>7 urinary incontinence with the use of mesh can cause</p> <p>8 permanent pelvic pain?</p> <p>9 A. Yes.</p> <p>10 Q. Is it also true that surgery for stress</p> <p>11 urinary incontinence without the use of mesh, in your</p> <p>12 opinion, can cause permanent dyspareunia?</p> <p>13 A. Yes.</p> <p>14 Q. Is it your opinion, Doctor, to a reasonable</p> <p>15 degree of medical certainty that surgery for stress</p> <p>16 urinary incontinence with the use of mesh can cause</p> <p>17 permanent dyspareunia?</p> <p>18 MR. DIPOLA: Object to form.</p> <p>19 A. Ask that question again.</p> <p>20 Q. Sure. Is it your opinion, Doctor, to a</p> <p>21 reasonable degree of medical certainty that surgery for</p> <p>22 stress urinary incontinence with the use of mesh or</p> <p>23 without can cause permanent dyspareunia?</p> <p>24 A. Yes.</p>

30 (Pages 114 to 117)

Michael Karram, M.D.

Page 118	Page 120
<p>1 Q. Is it also true for each of these outcomes</p> <p>2 that you have here, that surgery for stress urinary</p> <p>3 incontinence with the use of mesh can cause permanent</p> <p>4 scarring, vaginal narrowing, leg/groin pain, urinary</p> <p>5 retention and other voiding problems?</p> <p>6 A. And without mesh, both of them, yes.</p> <p>7 Q. So as a subset, is it your opinion that</p> <p>8 surgery for stress urinary incontinence without the use</p> <p>9 of mesh can cause permanent pelvic pain, dyspareunia,</p> <p>10 scarring, vaginal narrowing, leg/groin pain, urinary</p> <p>11 retention and other voiding problems?</p> <p>12 A. Yes.</p> <p>13 Q. Similarly, is it your opinion within a</p> <p>14 reasonable degree of medical certainty that surgery for</p> <p>15 stress urinary incontinence with the use of mesh can</p> <p>16 cause permanent pelvic pain, dyspareunia, scarring,</p> <p>17 vaginal narrowing, leg/groin pain, urinary retention and</p> <p>18 other voiding problems?</p> <p>19 MR. DIPOLA: Object to form.</p> <p>20 A. Yes.</p> <p>21 Q. You go on to discuss in this section some of</p> <p>22 the training that you've participated in, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. You say, "The process would begin with</p>	<p>1 A. In my opinion, yes.</p> <p>2 Q. And you also have the next sentence where you</p> <p>3 say, "It's a major portion of their practice." Is that</p> <p>4 part of what you mean by "qualified"?</p> <p>5 A. Correct.</p> <p>6 Q. In other words, for you, in this just brief</p> <p>7 description of a qualified surgeon, it would be a</p> <p>8 urogynecologist or gynecologist who's experienced and</p> <p>9 knowledgeable in the surgical management of stress</p> <p>10 urinary incontinence where it is a major portion of</p> <p>11 their practice? Is that a fair definition of qualified</p> <p>12 surgeon?</p> <p>13 A. Yes.</p> <p>14 Q. Doctor, would you think it inappropriate if</p> <p>15 Ethicon would identify surgeons that were not qualified</p> <p>16 and still attempt to sell these devices to those</p> <p>17 surgeons?</p> <p>18 MR. DIPOLA: Object to form.</p> <p>19 A. Ask it again.</p> <p>20 Q. Sure. Would you deem it inappropriate, in</p> <p>21 your opinion, if Ethicon knowingly attempted to sell</p> <p>22 these devices to surgeons that were not qualified as you</p> <p>23 describe here?</p> <p>24 MR. DIPOLA: Same objection.</p>
Page 119	Page 121
<p>1 representatives in the field serving qualified surgeons</p> <p>2 that might be interested in the use of these devices,"</p> <p>3 correct?</p> <p>4 A. Correct.</p> <p>5 Q. And by "representatives in the field," you</p> <p>6 mean the sales representatives from Ethicon?</p> <p>7 A. The Ethicon reps in the field, yes.</p> <p>8 Q. And the Ethicon reps in the field would</p> <p>9 initially identify potential candidates to use these</p> <p>10 devices, correct?</p> <p>11 MR. DIPOLA: Object to form.</p> <p>12 A. My understanding is yes.</p> <p>13 Q. And you define what you call here a qualified</p> <p>14 surgeon; is that right?</p> <p>15 A. Yes.</p> <p>16 Q. And you say, "A qualified surgeon would be a</p> <p>17 urogynecology or gynecologist who's experienced and</p> <p>18 knowledgeable in the surgical management of SUI,"</p> <p>19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. Is that important, do you think, that it is</p> <p>22 only these -- these products are only offered to</p> <p>23 qualified surgeons?</p> <p>24 MR. DIPOLA: Object to form.</p>	<p>1 A. Yes.</p> <p>2 Q. You then start to describe what a training</p> <p>3 session would look like in the next portion; is that</p> <p>4 right?</p> <p>5 A. That's correct.</p> <p>6 Q. And is this based, Doctor, on the way that you</p> <p>7 would do it?</p> <p>8 A. This is the way it was done.</p> <p>9 Q. And when you say "this is the way it was</p> <p>10 done," you meant that this is the way Ethicon had it set</p> <p>11 up to be done?</p> <p>12 MR. DIPOLA: Object to form.</p> <p>13 A. They ran the programs, yes, but we had a</p> <p>14 discussion as to how the training program should</p> <p>15 proceed, and it was a combination of surgeon input and</p> <p>16 company input.</p> <p>17 Q. Did you actually work with Ethicon designing</p> <p>18 the training programs?</p> <p>19 A. No.</p> <p>20 Q. You have presented at a number of training</p> <p>21 programs, correct?</p> <p>22 A. Correct.</p> <p>23 Q. Have you attended other training programs</p> <p>24 where you were not a presenter?</p>

31 (Pages 118 to 121)

Michael Karram, M.D.

Page 122	Page 124
<p>1 A. Yes.</p> <p>2 Q. Did you find that the way it was done was the</p> <p>3 same across the training programs?</p> <p>4 MR. DIPOLA: Object to form.</p> <p>5 A. Yes. For the most part, yes.</p> <p>6 Q. Was there a difference in training programs --</p> <p>7 well, let me put it this way. You say here, "At the</p> <p>8 training program, physicians will be given information</p> <p>9 on the products, the IFUs and clinical data to review</p> <p>10 before their training session," correct?</p> <p>11 A. That was what they were supposed to do, yes.</p> <p>12 Q. Who do you mean by "they"?</p> <p>13 A. The surgeons that were coming to be trained.</p> <p>14 Q. And it's your appreciation or was your</p> <p>15 appreciation that Ethicon would send the physicians who</p> <p>16 were coming to be trained materials ahead of time to</p> <p>17 review?</p> <p>18 A. Yes, or they were given information to say</p> <p>19 "review these things."</p> <p>20 Q. You then say, "The training session would be</p> <p>21 two days, Friday night an in-depth discussion between</p> <p>22 faculty and participants about indications,</p> <p>23 contraindications, technique, complications and</p> <p>24 management of the complications," right?</p>	<p>1 A. Correct.</p> <p>2 Q. Describe that day in a little more detail, if</p> <p>3 you could. What happens at 7:00 a.m.?</p> <p>4 A. 7:00 a.m. we would meet in the lecture hall.</p> <p>5 And then there would be a lecture about the product, and</p> <p>6 the slides that -- the prof ed slides. And then we</p> <p>7 would answer any questions. That usually went to about</p> <p>8 9:00.</p> <p>9 And then we went into the cadaver lab. And</p> <p>10 the cadaver, depending on how many participants were</p> <p>11 there and how many faculty members were there, usually</p> <p>12 was one faculty member per cadaver and one or two</p> <p>13 participants, sometimes three, on the cadaver.</p> <p>14 And then they would implant whatever procedure</p> <p>15 that we were teaching at the time. And then we would</p> <p>16 instruct them; "You did it correctly." You did it</p> <p>17 incorrectly." They would ask, "What if this happens,</p> <p>18 what do I do? Where do I go here? What am I doing</p> <p>19 wrong?" And we would instruct them.</p> <p>20 And then we would not allow them to leave</p> <p>21 until we felt confident that what we were trying to</p> <p>22 impress upon them they understood and they had the</p> <p>23 physical technique to do it.</p> <p>24 Q. Were people from Ethicon there as well during</p>
Page 123	Page 125
<p>1 A. That would be part of the discussion, yes. It</p> <p>2 was over dinner, and then after dinner.</p> <p>3 Q. I was going to say, is that then -- so a</p> <p>4 typical training session when you say it's two days</p> <p>5 would be the Friday night dinner portion and then the</p> <p>6 Saturday portion, correct?</p> <p>7 A. The cadaver portion would be Saturday,</p> <p>8 correct.</p> <p>9 Q. Okay. And the Friday night in-depth</p> <p>10 discussion between faculty and participants is something</p> <p>11 that occurs over dinner typically?</p> <p>12 A. Correct.</p> <p>13 Q. Would these trainings occur here in</p> <p>14 Cincinnati?</p> <p>15 A. Some of them were in Cincinnati, but the</p> <p>16 majority were outside of Cincinnati.</p> <p>17 Q. Was there a particular place that you would go</p> <p>18 for them, or were they across the country?</p> <p>19 A. They were across the country.</p> <p>20 Q. Were they always nice, warm places?</p> <p>21 A. No. Sometimes cold, snowy.</p> <p>22 Q. So on the second day of the training sessions,</p> <p>23 you describe as "Saturday would be a full day in the</p> <p>24 cadaver lab, 7 a.m. to 5 p.m."</p>	<p>1 these training sessions?</p> <p>2 A. They were there, but they were not on the</p> <p>3 cadavers. They were in the background.</p> <p>4 Q. Was there ever a situation where you finished</p> <p>5 a day and you told Ethicon, This guy or this woman, she</p> <p>6 just doesn't have it?</p> <p>7 A. Yes, yes.</p> <p>8 Q. Do you know what happened with that physician?</p> <p>9 MR. DIPOLA: Object to form.</p> <p>10 A. I do not.</p> <p>11 Q. Do you recall who it was?</p> <p>12 A. No.</p> <p>13 MR. DIPOLA: I'll let that one go.</p> <p>14 Q. So in your report, you say a didactic</p> <p>15 presentation followed by a cadaver lab where every</p> <p>16 participant under the supervision of the faculty would</p> <p>17 implant the device until you were satisfied they could</p> <p>18 do it, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. Is it your opinion, Doctor, that after someone</p> <p>21 has done cadaver lab to the level that you approve that</p> <p>22 person, that that person can now be qualified to go out</p> <p>23 and start using these devices?</p> <p>24 MR. DIPOLA: Object to form.</p>

32 (Pages 122 to 125)

Michael Karram, M.D.

Page 126	Page 128
<p>1 A. No. I mean, it depends on their previous 2 experience. You know, if I saw and knew somebody that 3 had done, you know, Burches his or her entire career and 4 has done all these other procedures, and then I watch 5 them, I would say they would probably be qualified, but 6 that really isn't my decision, and it wasn't Ethicon's 7 decision. It was their credentialing committee at the 8 hospital to make that decision as to whether they should 9 be credentialed to perform the procedure or not.</p> <p>10 Q. Do you understand at the end of these 11 sessions, Ethicon would give each of the physicians a 12 certificate of some sort, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Did you ever receive a certificate from 15 Ethicon on any of the devices?</p> <p>16 MR. DIPAOLO: Object to form.</p> <p>17 A. I think I did, yes.</p> <p>18 Q. Did you provide that to your credentialing 19 committee?</p> <p>20 A. I did.</p> <p>21 Q. So those certificates were something that you 22 at least personally used to demonstrate to your hospital 23 that you were a proper physician to try these 24 techniques, correct?</p>	<p>1 they might have changed it, and maybe they will one day.</p> <p>2 ---</p> <p>3 INVITATION BATES-STAMPED 4 ETH.MESH.00789838 WAS MARKED AS 5 EXHIBIT NO. 11. 6 ---</p> <p>7 Q. Let me just mark as Exhibit 11 -- Doctor, I've 8 handed you a document, and you see on the bottom right 9 corner it says ETH.MESH --</p> <p>10 A. Yes.</p> <p>11 Q. -- 00789838, correct?</p> <p>12 A. Yes.</p> <p>13 Q. This is from the production that was given to 14 us by Ethicon, and it's an invitation to Advanced Pelvic 15 Floor Course, Course 2. Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And you are one of the faculty, correct?</p> <p>18 A. I am.</p> <p>19 Q. Along with --</p> <p>20 A. Tamera Howell.</p> <p>21 Q. Dr. Howell?</p> <p>22 A. Right.</p> <p>23 Q. Is this a reflection of one of the two-day 24 courses that you were discussing?</p>
Page 127	Page 129
<p>1 MR. DIPAOLO: Object to form.</p> <p>2 A. No. Just that I was a physician that attended 3 a two-day Ethicon-sponsored course, and I implanted the 4 device on a cadaver once or twice or three times or four 5 times.</p> <p>6 Q. In some of the prof ed that you -- some of 7 these sessions that you participated in, were there 8 multiple devices actually done?</p> <p>9 MR. DIPAOLO: Objection.</p> <p>10 Q. In other words, would you do sometimes the 11 TVT-R as well as the TVT Obturator?</p> <p>12 A. Yes.</p> <p>13 Q. Would those be longer courses or the same?</p> <p>14 A. The same.</p> <p>15 Q. Were all of the courses two days? Because 16 I've got some materials showing that maybe they weren't.</p> <p>17 A. The ones that I participated in were usually 18 the two days where we came in that Friday evening and 19 had the dinner and discussion, and then Saturday was all 20 day cadavers, and usually most people departed in the 21 evenings.</p> <p>22 Now, with -- I mean, that's when we used to 23 have nonstop flights most places and you could get in 24 and out quick. Now, with all this connection stuff,</p>	<p>1 A. No. This was a one-day course.</p> <p>2 Q. Is that because it's an advanced course?</p> <p>3 A. Yes, I think so.</p> <p>4 Q. Okay.</p> <p>5 A. If I remember right, yes.</p> <p>6 Q. So if you look in the box in the bottom, it 7 says, "A representative will pick up attendees in the 8 hotel lobby at 7:00 a.m. Course will end by 2 p.m." 9 Correct?</p> <p>10 A. Correct.</p> <p>11 Q. So this is not a two-day course. This is 12 actually more like a half-day course; is that fair?</p> <p>13 A. Correct.</p> <p>14 Q. So you did participate in some of these 15 courses where at the end of the half-day course, the 16 physician would, indeed, get a certificate, correct?</p> <p>17 A. But these were trained physicians that have 18 already had experience with either these devices or 19 devices from other companies that they weren't happy 20 with, and so they just wanted to compare. These were 21 not new trainees that have never done TVTs before.</p> <p>22 Q. And, hence, the advanced?</p> <p>23 A. Correct.</p> <p>24 Q. So these would be the physicians whom Ethicon</p>

33 (Pages 126 to 129)

Michael Karram, M.D.

Page 130	Page 132
<p>1 representatives, sales representatives, have identified</p> <p>2 as more qualified than a first timer, for example, and</p> <p>3 so you could do a shorter course?</p> <p>4 MR. DIPAOLA: Object to form.</p> <p>5 A. Or the surgeon could have contacted Ethicon as</p> <p>6 well. It doesn't necessarily have to be the rep. The</p> <p>7 surgeon could say, hey, I'm doing these procedures with</p> <p>8 this device. I'm not happy with it. Do you have any</p> <p>9 advanced courses where we can learn or at least see what</p> <p>10 your products are like?</p> <p>11 Q. But it's your testimony that this was not the</p> <p>12 norm for professional education?</p> <p>13 A. This was not, correct, and usually there's</p> <p>14 more than just two faculty members as well on the norm,</p> <p>15 the bigger ones.</p> <p>16 ---</p> <p>17 INVITATION BATES-STAMPED</p> <p>18 ETH.MESH.01678144 WAS MARKED AS</p> <p>19 EXHIBIT NO. 12.</p> <p>20 ---</p> <p>21 Q. I'm going to hand you Exhibit 12. It's</p> <p>22 another flyer for Advanced Pelvic Floor Course.</p> <p>23 A. Okay.</p> <p>24 Q. And, indeed, this one has more than two</p>	<p>1 work, correct?</p> <p>2 A. Correct.</p> <p>3 Q. How would you bill for that? Is it an hourly</p> <p>4 billing, or is it by day?</p> <p>5 A. It was a set fee.</p> <p>6 Q. It was a set fee?</p> <p>7 A. It was a set fee.</p> <p>8 Q. No matter how many hours you put in?</p> <p>9 A. Correct, yeah.</p> <p>10 MR. DIPAOLA: Asked and answered.</p> <p>11 ---</p> <p>12 SPREADSHEET BATES-STAMPED</p> <p>13 ETH.MESH.04181701 WAS MARKED AS</p> <p>14 EXHIBIT NO. 13.</p> <p>15 ---</p> <p>16 Q. I'm going to hand you what is being marked as</p> <p>17 Exhibit 13. Doctor, I've handed you what has been</p> <p>18 marked as Exhibit 13.</p> <p>19 A. Okay.</p> <p>20 Q. It's a spreadsheet that was produced to us by</p> <p>21 Ethicon, and it lists preceptors. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Then it has the event date; is that right?</p> <p>24 A. Yes.</p>
Page 131	Page 133
<p>1 trainers, correct?</p> <p>2 A. Correct.</p> <p>3 Q. And this was another half-day course, correct?</p> <p>4 A. This was.</p> <p>5 MR. DIPAOLA: Objection.</p> <p>6 A. Actually, it was a full-day course. It went</p> <p>7 to 3:15. I would consider that a full-day course.</p> <p>8 Q. Where it says "A representative will pick up</p> <p>9 attendees in the hotel lobby at 7:30. Course will end</p> <p>10 by 3:15."</p> <p>11 A. 3:15.</p> <p>12 Q. Were you the one deciding how long the course</p> <p>13 should be?</p> <p>14 A. No.</p> <p>15 Q. Who decided that?</p> <p>16 A. The company.</p> <p>17 Q. Would you consider a full day to be an</p> <p>18 eight-hour billing for you?</p> <p>19 A. An eight-hour billing?</p> <p>20 MR. DIPAOLA: Object to form.</p> <p>21 Q. Let me ask that better.</p> <p>22 For Exhibit 12 that we were just looking at --</p> <p>23 A. Yes.</p> <p>24 Q. -- you would be paid by Ethicon for doing that</p>	<p>1 Q. This is for a time frame of 2008. That's most</p> <p>2 of the dates, correct?</p> <p>3 A. Yes.</p> <p>4 Q. Then it has the event name, the location, the</p> <p>5 time spent, the amount paid, and the date that the</p> <p>6 payment was sent to the preceptor, correct?</p> <p>7 A. Correct.</p> <p>8 Q. If you go down this list, for example, and you</p> <p>9 look at just the "Prolift/SECUR cadaver lab," so the</p> <p>10 fourth line down. It's actually Brian Flynn from</p> <p>11 Denver, Colorado, right?</p> <p>12 A. Yes.</p> <p>13 Q. It has six physicians, I think. Yes, six</p> <p>14 physicians who taught at that lab on 4/2/2008, correct?</p> <p>15 A. Okay. Yes.</p> <p>16 Q. You'll see to the right it says, "Time spent,</p> <p>17 eight hours" on each of those, right?</p> <p>18 A. Correct.</p> <p>19 Q. So would that be in your --</p> <p>20 A. Well, no, it says Flynn was only there for</p> <p>21 four hours, and then Easter was there for eight, and</p> <p>22 Aguirre was there for eight.</p> <p>23 Q. You know all those guys, right?</p> <p>24 A. I know Aguirre and Mike Woods. I've met</p>

34 (Pages 130 to 133)

Michael Karram, M.D.

Page 134	Page 136
<p>1 Brian, but I wouldn't say I know him. I don't know Tom</p> <p>2 Easter.</p> <p>3 Q. I met Brian last week, just like this.</p> <p>4 MR. DIPOLA: Just a point of accuracy, this</p> <p>5 is not on the same event date. The 4/3 and 4/7 are</p> <p>6 Easter and Aguirre. The rest are not on 4/2 -- the rest</p> <p>7 are on 4/2. Easter and Aguirre are not on 4/2, so I'm</p> <p>8 not quite what you're asking.</p> <p>9 Q. If you turn to the last page, Doctor, six</p> <p>10 down, I think you'll recognize that name.</p> <p>11 A. The last page, six down, I have no idea who</p> <p>12 that is. Who is that?</p> <p>13 MR. DIPOLA: Just I think --</p> <p>14 THE WITNESS: Yeah, I know.</p> <p>15 MR. DIPOLA: You were kidding. I thought you</p> <p>16 were on the wrong page.</p> <p>17 A. Yes. I see it.</p> <p>18 Q. Six down, and that's you, correct?</p> <p>19 A. That's me, that's correct.</p> <p>20 Q. So this appears to report that on</p> <p>21 February 18th, 2009, you taught a TVT-O preceptorship in</p> <p>22 Cincinnati, Ohio, correct?</p> <p>23 A. That is correct.</p> <p>24 Q. And it shows four hours, and a billing of</p>	<p>1 by the time we got there.</p> <p>2 So it's fair to say, Doctor, if we turn back</p> <p>3 to your report, Exhibit 2, that in the section where</p> <p>4 you're discussing training and you're discussing a</p> <p>5 two-day training session, that your recollection is that</p> <p>6 that's for essentially first-time surgeons; is that</p> <p>7 fair?</p> <p>8 A. First-time surgeons that are using other</p> <p>9 techniques and want to learn or be educated on TVT.</p> <p>10 Q. And those would be the two-day seminars. For</p> <p>11 more advanced surgeons, those seminars could be as short</p> <p>12 as a half day?</p> <p>13 A. Correct.</p> <p>14 Q. And they would all receive a certificate that</p> <p>15 they could provide to their credentialing board?</p> <p>16 MR. DIPOLA: Object to form.</p> <p>17 A. One would be only for four hours. The other</p> <p>18 would be for --</p> <p>19 Q. You go on to discuss what we were just talking</p> <p>20 about, surgeon credentialing, and then on to adequacy of</p> <p>21 company IFU and patient brochures.</p> <p>22 A. Right.</p> <p>23 Q. And I think we discussed earlier that in the</p> <p>24 three or so months leading up to drafting your report</p>
Page 135	Page 137
<p>1 \$1,750, correct?</p> <p>2 A. Correct.</p> <p>3 Q. Is that consistent with your memory of how you</p> <p>4 would do preceptorships? They would be about four</p> <p>5 hours, and that was your pay for a preceptorship?</p> <p>6 MR. DIPOLA: Object to form.</p> <p>7 A. Yes. But if I remember right, this was a</p> <p>8 little different. This was a group of surgeons that</p> <p>9 came in. This was a program that we did here where we</p> <p>10 brought them in that night, if I remember right. Yeah,</p> <p>11 because these are the only ones I did in Cincinnati,</p> <p>12 unless -- well, maybe not.</p> <p>13 But we were doing proctorships or bringing</p> <p>14 surgeons in to watch me do surgery, and then we would go</p> <p>15 over -- so we'd do a half day in the OR, and they would</p> <p>16 actually watch me in the OR. And then we would go over</p> <p>17 to UC and do the cadaver lab, and so that would only be</p> <p>18 four hours. That's different than these programs.</p> <p>19 Q. Because these are the preceptorships?</p> <p>20 A. These were more the doctors wanted to see the</p> <p>21 surgery being done in person.</p> <p>22 Q. And then you appear again --</p> <p>23 A. I don't see me again.</p> <p>24 Q. It's on a different page. It would be complex</p>	<p>1 and in the drafting of your report, you didn't</p> <p>2 necessarily review any IFUs or patient brochures during</p> <p>3 that time frame, correct?</p> <p>4 A. Correct.</p> <p>5 Q. When you're writing your opinions here about</p> <p>6 the IFU and the patient brochures, are those based upon</p> <p>7 your historical experience with those documents?</p> <p>8 A. Yes.</p> <p>9 MR. DIPOLA: Object to form.</p> <p>10 Q. They weren't specifically reviewed for</p> <p>11 drafting of your report; is that fair?</p> <p>12 MR. DIPOLA: Object to form.</p> <p>13 A. Correct.</p> <p>14 Q. And there again in this section, you have a</p> <p>15 statement, "All patients are consented and understand</p> <p>16 the risk, benefits, options and complications."</p> <p>17 A. Correct.</p> <p>18 Q. Again, that's not something that you know for</p> <p>19 an absolute fact that all patients are consented, nor do</p> <p>20 you know for a fact that all patients understand,</p> <p>21 correct?</p> <p>22 A. Well, I --</p> <p>23 Q. I have to ask.</p> <p>24 A. Yeah, and I have to answer. Yes, all patients</p>

35 (Pages 134 to 137)

Michael Karram, M.D.

Page 138	Page 140
<p>1 are consented; otherwise, they can't go into surgery. 2 Every patient has to be consented. 3 Q. In your practice? 4 A. In any practice. Nobody can go into the OR in 5 the United States without a consent form being signed by 6 the patient; or if they can't sign it, whoever is 7 responsible for them. So they are consented. 8 Now, I know for a fact that all these teaching 9 programs that we had, we always spoke about consent, how 10 to consent somebody, what you have to tell them, et 11 cetera, et cetera. So, no, I have not talked to every 12 surgeon and say, "Do they consent this way?" But I 13 would say there's a uniform acceptance of a consent form 14 when it comes to a synthetic sling. 15 Q. So, again, we've discussed that you haven't 16 looked at any internal Ethicon documents, nor have you 17 read any of the Ethicon employee depositions, correct? 18 A. Correct. 19 MR. DIPAOLA: Object. 20 Q. So, you know, if one of Ethicon's employees 21 had testified that she would receive telephone calls 22 from women who would say, "I had no idea that I could 23 have permanent pain every time I have sexual 24 intercourse. Nobody ever told me that." You don't have</p>	<p>1 Q. But it's your opinion that they all understand 2 that consent? That's what you say in your expert 3 report, correct? 4 MR. DIPAOLA: Object to form. 5 A. Yes. 6 Q. And is it your opinion that if a woman says 7 that she didn't understand the risks, that she's lying? 8 MR. DIPAOLA: Object to form. 9 A. No, I didn't say that. I'm saying that she 10 might not have understood what they were telling her. 11 But when you consent somebody, you list all the possible 12 complications that could be occurring, and you do that 13 both in a mesh and a non-mesh procedure. 14 (Discussion held off the record.) 15 MR. ZONIES: I'll reserve my two minutes if 16 you're going to have questions. 17 MR. DIPAOLA: I have maybe five minutes' 18 worth. 19 MR. ZONIES: That's great. 20 - - - 21 EXAMINATION 22 BY MR. DIPAOLA: 23 Q. Dr. Karram, just going over some points that 24 Plaintiff counsel was asking you over the last three</p>
Page 139	Page 141
<p>1 any way to know whether or not she was actually properly 2 consented -- 3 MR. DIPAOLA: Objection. 4 Q. -- correct? 5 MR. DIPAOLA: Total hearsay. Assumes facts 6 not in evidence. You could go on and on. 7 A. I could say the same thing. I have a patient 8 come to me. I do an exam. She doesn't have a uterus. 9 I say, "When did you have a hysterectomy?" She says, "I 10 didn't even know I had a hysterectomy." Was she 11 consented correctly for her hysterectomy? 12 Q. Would it be fair then to say she didn't 13 understand that she had a hysterectomy? 14 MR. DIPAOLA: Object to form. 15 A. No. I think it's fair to say that probably 16 they are not either telling the truth, or they 17 misrepresent the truth, or they're trying to get 18 something else out of whatever they're trying to 19 discuss. 20 But, no, I think anybody who has surgery has 21 to be consented. And if you remember, the FDA came out 22 with a notice in 2008 and 2011, and both of those had 23 something to do with consent. So patients have to be 24 consented, and they are consented.</p>	<p>1 hours minus two minutes, is it your opinion that Ethicon 2 bears no responsibility to decide who is qualified to do 3 a particular procedure, and, indeed, that responsibility 4 lies with the individual hospital's credentialing 5 committee? 6 MR. ZONIES: Object to form. 7 A. Yes. 8 Q. Remember when Plaintiff's counsel was 9 questioning you about the Ulmsten report? 10 A. Yes. 11 Q. And, if you will, questions were put forth 12 that the representation in your general report of a 13 slide in the Ulmsten paper had some parallax -- my word, 14 not his -- had some parallax issues, correct? 15 A. Correct. 16 Q. If one goes to the original Ulmsten chart on 17 page 349 of that study and the numbers that are above 18 the bar graphs between the 12-month success rates and 19 the 24/36-month success rates, are those numbers the 20 same? 21 A. They are. 22 Q. Would that imply to you that at least for the 23 36 months that this study was represented by this bar 24 graph, that the repairs were essentially stable over the</p>

36 (Pages 138 to 141)

Michael Karram, M.D.

Page 142	Page 144
<p>1 years between 12 months and 36 months?</p> <p>2 MR. ZONIES: Object to form.</p> <p>3 A. Yes.</p> <p>4 Q. Do you remember the TOMUS study?</p> <p>5 A. Yes.</p> <p>6 Q. Would you agree with me that the TOMUS study</p> <p>7 was -- and Plaintiff's counsel used the equivalency</p> <p>8 terminology. This study was a study that attempted to</p> <p>9 decide the difference, if any, between TVT-R and TVT-O</p> <p>10 when used to correct stress urinary incontinence; would</p> <p>11 that be a fair statement?</p> <p>12 A. That would, yes.</p> <p>13 Q. This study was in no way designed to decide</p> <p>14 whether mesh tapes in midurethral sling positions were</p> <p>15 any better or worse than any preceding operations that</p> <p>16 did not include mesh, correct?</p> <p>17 A. That's correct.</p> <p>18 Q. And, indeed, what the study really found was</p> <p>19 that the benefits of TVT-R carried over to TVT-O when</p> <p>20 they were compared head to head?</p> <p>21 MR. ZONIES: Object to form.</p> <p>22 A. That's correct, with less complications.</p> <p>23 Q. Do you remember when Plaintiffs' counsel also</p> <p>24 asked you whether you were a biomaterials expert?</p>	<p>1 materials, correct?</p> <p>2 A. I am not.</p> <p>3 Q. You say in your last sentence on the next page</p> <p>4 in that section, "They should be considered safe until</p> <p>5 scientific data proves otherwise." Do you believe that</p> <p>6 to be the standard of how to determine the safety of a</p> <p>7 medical device?</p> <p>8 MR. DIPOLA: Object to form.</p> <p>9 A. Come again?</p> <p>10 Q. Do you believe your statement that "They</p> <p>11 should be considered safe until scientific data proves</p> <p>12 otherwise," do you believe that to be the standard by</p> <p>13 which you would judge the safety of a medical device?</p> <p>14 MR. DIPOLA: Object to form; misstates.</p> <p>15 A. You have to go by the evidence and the data</p> <p>16 that you have at this time. And based on the data that</p> <p>17 we have at this time, there is no evidence to show that</p> <p>18 there's any carcinogenesis related to these slings.</p> <p>19 Q. Is it your opinion --</p> <p>20 A. Now, maybe in 10 years or 15 or 20 years,</p> <p>21 something else might show up that's different. That's</p> <p>22 what I'm implying when I say that statement.</p> <p>23 Q. Fair enough. Thank you for your time, Doctor.</p> <p>24 A. Anytime.</p>
Page 143	Page 145
<p>1 A. Yes.</p> <p>2 Q. Do you remember what you answered to that?</p> <p>3 A. I said no.</p> <p>4 Q. Whereas you're not a biomaterials expert, as</p> <p>5 an expert urogynecologist who has implanted, in your</p> <p>6 words, over 2,000 slings, are you an expert in how a</p> <p>7 woman's body reacts to implanted mesh?</p> <p>8 MR. ZONIES: Object to form.</p> <p>9 A. I would consider myself an expert, yes.</p> <p>10 Q. As you sit here today, do you believe that</p> <p>11 midurethral slings are the gold standard of current</p> <p>12 therapy in treating women with stress urinary</p> <p>13 incontinence?</p> <p>14 MR. ZONIES: Object to the form.</p> <p>15 A. Yes.</p> <p>16 MR. DIPOLA: I have nothing else.</p> <p>17 - - -</p> <p>18 FURTHER EXAMINATION</p> <p>19 BY MR. ZONIES:</p> <p>20 Q. Doctor, just a follow-up. In the next section</p> <p>21 of your report it's entitled, "Malignant Potential of</p> <p>22 Mesh." Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. You are not an expert in carcinogenicity of</p>	<p>1 MR. DIPOLA: We're not going to waive.</p> <p>2 (Signature not waived.)</p> <p>3 - - -</p> <p>4 Thereupon, at 2:36 p.m., on Tuesday, March 29,</p> <p>5 2016, the deposition was concluded.</p> <p>6 - - -</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

37 (Pages 142 to 145)

Michael Karram, M.D.

Page 146	Page 148
<p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2 I, _____, do</p> <p>3 hereby certify that I have read the</p> <p>4 foregoing pages, and that the same</p> <p>5 is a correct transcription of the answers</p> <p>6 given by me to the questions therein</p> <p>7 propounded, except for the corrections or</p> <p>8 changes in form or substance, if any,</p> <p>9 noted in the attached Errata Sheet.</p> <p>10 _____</p> <p>11 MICHAEL KARRAM, M.D. DATE</p> <p>12</p> <p>13</p> <p>14</p> <p>15 Subscribed and sworn</p> <p>16 to before me this</p> <p>17 _____ day of _____, 20____.</p> <p>18 My commission expires: _____</p> <p>19 _____</p> <p>20 Notary Public</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 REASON: _____</p> <p>7 REASON: _____</p> <p>8 REASON: _____</p> <p>9 REASON: _____</p> <p>10 REASON: _____</p> <p>11 REASON: _____</p> <p>12 REASON: _____</p> <p>13 REASON: _____</p> <p>14 REASON: _____</p> <p>15 REASON: _____</p> <p>16 REASON: _____</p> <p>17 REASON: _____</p> <p>18 REASON: _____</p> <p>19 REASON: _____</p> <p>20 REASON: _____</p> <p>21 REASON: _____</p> <p>22 REASON: _____</p> <p>23 REASON: _____</p> <p>24 REASON: _____</p>
<p>Page 147</p> <p>1 CERTIFICATE</p> <p>2 STATE OF OHIO :</p> <p>3 SS:</p> <p>4 COUNTY OF FRANKLIN :</p> <p>5 I, Carol A. Kirk, a Registered Merit Reporter</p> <p>6 and Notary Public in and for the State of Ohio, duly</p> <p>7 commissioned and qualified, do hereby certify that the</p> <p>8 within-named MICHAEL KARRAM, M.D., was by me first duly</p> <p>9 sworn to testify to the truth, the whole truth, and</p> <p>10 nothing but the truth in the cause aforesaid; that the</p> <p>11 deposition then given by him was by me reduced to</p> <p>12 stenotype in the presence of said witness; that the</p> <p>13 foregoing is a true and correct transcript of the him so</p> <p>14 given by him; that the deposition was taken at the time</p> <p>15 and place in the caption specified and was completed</p> <p>16 without adjournment; and that I am in no way related to</p> <p>17 or employed by any attorney or party hereto or</p> <p>18 financially interested in the action; and I am not, nor</p> <p>19 is the court reporting firm with which I am affiliated,</p> <p>20 under a contract as defined in Civil Rule 28(D).</p> <p>21</p> <p>22 IN WITNESS WHEREOF, I have hereunto set my</p> <p>23 hand and affixed my seal of office at Columbus, Ohio on</p> <p>24 this 1st day of April 2016.</p> <p>_____</p> <p>CAROL A. KIRK, RMR</p> <p>NOTARY PUBLIC - STATE OF OHIO</p> <p>My Commission Expires: April 8, 2017.</p> <p>---</p>	

38 (Pages 146 to 148)

Michael Karram, M.D.

Page 149

A	addition 4:9 7:16 30:1 103:11	93:8 96:3 122:16	143:2	ARTICLE 4:16 4:19,22 96:6 108:12 110:12
A-U-G-S 55:17	additional 14:6	al 68:2	answering 116:3	articles 31:1 53:24 54:2 76:3,9,12,20 81:20 82:3 95:4
a.m 1:14 3:2 123:24 124:3,4 129:8	addressing 29:9 71:7	Alabama 2:10	answers 146:4	
AAGL 35:22	adds 106:13 108:7	allegation 70:6 72:16 73:21 74:4,10	anterior 101:9 101:20,23	
Abbrevo 29:14 58:20,22 85:19 86:3,5,15,17 86:21,23 87:3 87:8,9,13,22 88:13,23 89:3 89:12,17	adequacy 136:20	allegations 72:6 74:18 75:1,3	Anterior/Post... 44:9	
Abbrevos 92:12	adjournment 147:9	alleges 72:7	Anthem 72:11	artificially 70:3 74:21
abdomen 105:3	advanced 5:3,5 128:14 129:2 129:22 130:9 130:22 136:11	alleging 66:19 68:10 69:8	antitrust 66:15 67:23 68:19 69:6	aside 19:13 20:16,18,24 28:12
absence 74:9	advantages 64:5 64:8	ALLEN 2:9	anymore 85:24 89:14 92:23	asked 24:13 25:4,8 35:23 66:4,23 83:4 85:6 91:17 132:10 142:24
absolute 137:19	adverse 98:22 98:24	allow 124:20	Anytime 144:24	asking 134:8 140:24
absolutely 25:12 59:12	advisement 103:3	America 66:13 66:18 69:20 70:15	apart 59:5	assessed 96:22 97:4
abstract 76:4 97:3 108:21 109:1	advisory 40:12 41:5,19	American 1:17 44:2	Apogee 44:8	assume 34:18 41:3 49:3
abstracts 54:1 76:12 95:6	Aetna 74:15	amount 16:18 16:24 18:13 46:14 47:13 61:3 133:5	apologize 92:10	assumed 89:18
acceptance 138:13	affiliated 147:11	amounted 18:12	apparently 89:19	assumes 113:10 139:5
accuracy 134:4	affixed 147:13	AMS 44:4,7,15 44:21,24 57:2 57:6,10,14,18 58:2,3 59:6 83:12 84:4,8,9 87:21 88:16 89:23	appear 21:24 135:22	assuming 92:17
accurate 24:2 34:20 43:18,19 44:12 114:7	aforesaid 147:6		APPEARAN... 2:2	Atlas 62:10,16
ACKNOWLEDGE... 146:1	agency 19:11		applicable 3:8 77:11	atrophic 38:5
act 66:15 68:15 69:14 74:21	ago 10:6,7 23:1 25:7 40:20 41:1 50:13 55:3,7 86:3		appreciation 53:6 122:14,15	attached 11:3 146:6
acting 107:10	agree 60:4 65:7 72:19 104:12 106:17 111:8 112:14 142:6	analyze 52:18	approach 58:9 60:17,21 61:7 89:9	attempt 120:16
action 66:12 147:10	agreement 15:9 16:16,18,19,20 16:23,24 70:3	analyzed 77:10	approached 55:6	attempted 120:21 142:8
actions 75:13	agreements 14:23 15:2 16:23 45:13	anatomical 61:4	approve 107:18 125:21	attempts 72:10
activity 71:7	Aguirre 133:22 133:24 134:6,7	anatomy 59:2 62:10	approximately 18:6 49:18 102:2	attended 11:19 121:23 127:2
Actonel 36:15 36:19,21 41:7 41:8,10 42:3 42:12,13	ahead 9:21 10:15 67:5	annual 17:13,17 44:20	April 147:13,17	attendees 129:7 131:9
actual 105:13		annually 70:15	area 66:21 70:5 71:10,23 74:1 74:4,8,20	attorney 47:15 147:10
add 105:16 108:7		answer 45:12 83:18 124:7 137:24		attorneys 54:10
		answered 83:4 85:7 91:17 116:4 132:10		AUGS 55:17 95:23 112:16 112:22,23
				August 4:14

67:9,18 author 31:3,5,18 31:23 95:18 96:14 authors 62:18 62:19 available 90:3 92:18,19,21 94:5 103:17 112:9 average 101:7,9 aware 14:18 17:11 61:17 67:4 80:24 104:4 107:19 114:5	8:19,20 15:19 19:1 36:21 48:6 49:24 107:11 belief 89:3 114:9 114:12 believe 20:14 21:1 29:24 34:21 52:13,24 61:11,19 64:10 65:2,19,23 83:7 84:2,6,19 88:11 91:20 97:13 143:10 144:5,10,12 bench 85:3 benefits 74:2 137:16 142:19 best 57:23 58:5 58:6 88:11 better 12:13 61:4 63:22 71:20 72:1 87:10 93:13 131:21 142:15 beyond 102:8 bigger 130:15 biggest 59:3 90:16 bill 28:21 132:3 billing 14:11 131:18,19 132:4 134:24 biomaterials 51:2 142:24 143:4 bladder 59:16 61:3,5 65:8 93:19 94:2 99:19 104:13 104:19,22,24 105:4,5,6,7,8,9 105:11,12,17 105:21 blank 114:9 Blind 31:13 blue 91:5	board 40:12 41:5,19 75:10 136:15 body 76:15,19 76:23 81:24 91:6 143:7 Boggs 1:9 28:3 bone 93:18 book 19:10 62:12 books 62:14 borne 70:5 bottom 31:14 55:16 68:22 80:22 128:8 129:6 bought 33:11 40:9 bowel 48:4 99:19 box 129:6 brachial 46:21 49:14 56:9 break 88:2,5 breakdown 56:17 breast 32:18 Brian 133:10 134:1,3 brief 120:6 briefly 45:22 bring 9:15 10:10 14:12,16,18,21 21:18 bringing 135:13 brochures 81:13 136:21 137:2,6 broken 27:3,6 brother 30:9 62:15 103:9 brothers 30:10 brought 10:14 11:1 24:5,6 66:12,18 69:18 135:10 Brown 1:16 bulk 82:18	bullet 105:20 Burch 59:24 60:2,4 63:1,1,2 63:5,13,16 64:10,12 101:11 103:23 104:14,20,23 105:2,10,13,14 105:21 Burches 126:3 busy 37:19 39:24 Butler 2:15 9:2 25:9 53:23	career 13:24 45:15 56:23 94:23 101:18 102:12 126:3 Carol 1:21 147:4,15 carried 142:19 case 1:8,8,9,9,10 1:10 25:5 27:3 27:21,24 46:1 46:5,10,11,16 46:22,24 47:4 47:6,8 48:1,3 48:15,21 49:4 49:21 50:2,13 50:15 56:9 68:20 69:19 71:12 81:12,16 94:19 96:19 case-specific 26:22 27:2,20 27:23 28:2,15 cases 27:18 28:16,19 50:5 50:10 55:5,7 60:18 109:8 catch 95:7 catheter 105:9 cause 114:20 115:7,17,21 116:9,15,19 117:4,7,12,16 117:23 118:3,9 118:16 147:6 CDs 10:11 Centers 32:6 certain 17:20 22:8,8 58:8,10 65:23 89:12 114:6,24 certainty 117:15 117:21 118:14 certificate 126:12,14 129:16 136:14 147:1 certificates
<hr/> B <hr/> B 73:24 baby 46:2,4,12 46:21 back 10:9 14:9 19:22 27:14 34:11,22,24 35:1 67:1 77:6 79:20 83:21 108:2 136:2 background 94:22 125:3 Baggish 62:16 Balloon 35:15 bar 110:4,6,7 141:18,23 base 61:14 based 25:13,16 61:15 71:18,19 121:6 137:6 144:16 basically 41:11 basis 57:17 72:4 BATES- 5:3 BATES-STA... 5:5,7 128:3 130:17 132:12 bears 141:2 BEASLEY 2:9 behalf 2:13,18			<hr/> C <hr/> C 7:2 C-y-t-e-c 38:12 cadaver 12:6 15:12 123:7,24 124:9,10,12,13 125:15,21 127:4 133:9 135:17 cadavers 125:3 127:20 calculator 25:11 call 27:7,17 87:2 93:5 119:13 called 3:7 32:12 36:15 37:10 58:4 71:8 75:23 77:18 calls 138:21 Caminiti 47:19 47:21,22 candidates 119:9 caption 27:17 147:9 capturing 95:9 carcinogenesis 144:18 carcinogenicity 143:24 care 37:20 46:15 65:16	

Michael Karram, M.D.

Page 151

126:21 certified 7:21 certify 70:15 146:3 147:5 cetera 78:24 138:11,11 chad.cook@b... 2:12 CHADWICK 2:9 chance 53:12 chances 53:15 change 107:24 109:22 148:3 changed 128:1 changes 107:14 107:19,20 146:5 character 3:12 characteristics 84:12,24 CHARLEST... 1:2 chart 98:22,24 100:11 108:3 110:4,6,7 141:16 Check 105:7 Cheyenne 48:11 choice 58:21 76:19 ChoiceCare 72:22 choices 76:18 choose 11:8 12:7 13:18 14:2 33:24 57:18 60:16,20 77:6 82:9 88:12 89:23 92:19,23 95:21 choosing 60:9 chose 57:20 89:2 97:17 chosen 89:8 Christmas 84:1 Cincinnati 1:18	30:18 47:12 49:9 66:21 69:11 70:5 71:10 74:1,4,8 123:14,15,16 134:22 135:11 circumstances 58:10 cite 31:5,20,22 76:15,18,24 77:9,14 82:6,9 97:17,18 cited 76:23 citing 77:4 106:3 city 71:13 civil 3:8 69:5 75:12 147:11 clarification 66:23 clarifies 87:24 clarify 87:19 cleaner 90:13 93:7 clear 105:15 clinical 23:4,9 23:10 35:14 51:24 122:9 clinically 84:14 97:24 98:3,7 close 105:3,9 closed 33:11 Cochrane 82:2,5 95:14 cold 123:21 Colony 2:15 Colorado 2:5 133:11 colporrhaphy 101:9,20 colposuspension 101:10 Columbus 147:13 column 67:21 combination 73:22 121:15 combined 22:20	63:5 come 34:3 43:10 71:17 103:3 139:8 144:9 comes 16:4 138:14 comfortable 95:9 coming 122:13 122:16 commerce 2:10 69:13 commercial 68:14 commission 146:16 147:17 commissioned 147:5 committee 126:7,19 141:5 common 104:14 104:19 105:21 commonly 96:15 communicated 21:2 communicatio... 20:10 companies 39:22 40:8,9 71:1,18,24 72:3 74:1 129:19 company 32:23 38:15 45:7,7 107:7 113:16 121:16 131:16 136:21 comparable 64:10,11 compare 129:20 compared 58:15 61:19 90:12 91:10 111:9 142:20 comparing 103:23	compensated 15:22 16:13,17 33:5,19 35:4 36:7,9,20,24 38:8,22 44:16 compensation 18:7 19:14 competition 41:14 66:21 74:3 Competitive 67:24 complaint 68:10 69:6,18 70:3,7 70:9,23 71:6,7 72:6 73:12 completed 147:9 completely 92:15 complex 60:19 60:23 135:24 complication 65:7,8 complications 46:3 94:1 114:21,24 115:7,12 122:23,24 137:16 140:12 142:22 complying 70:16 computer 21:14 22:2 100:15,20 102:20,21 103:5,13,17 111:24 112:9 concluded 145:5 conclusions 96:21 conferences 76:13 confidence 98:5 98:6 confident 124:21 connection	127:24 consent 70:10 70:12,16 138:5 138:9,10,12,13 139:23 140:2 140:11 consented 137:15,19 138:1,2,7 139:2,11,21,24 139:24 consider 15:12 16:6 51:6,8,12 51:16,20 52:2 52:5,8 60:12 76:22 101:7 131:7,17 143:9 considered 71:11 144:4,11 consistent 99:5 135:3 conspiracy 69:12 73:23 conspired 66:20 68:13 consult 40:6 consultancies 45:5 consultancy 33:7 39:19 consultant 15:23 18:8 32:21 34:7 35:20 36:5,12 36:16 37:6,24 38:11,24 40:1 42:21 43:2,6 44:1 107:10 consulting 14:23 15:2,9,10 16:2 17:1,10 19:13 45:13 CONT'D 5:1 contacted 130:5 continue 40:6 57:24 continuing
---	--	--	--	--

Michael Karram, M.D.

Page 152

70:13 contraceptive 37:8,11,21,22 contraceptives 38:16 contract 20:16 35:4 147:11 contracts 17:13 17:17 19:17 21:1 34:22,24 35:2,8,10 44:20,20 72:11 contraindicati... 122:23 control 52:11,21 53:2,5 controls 52:23 conversations 55:2 COOK 2:9 copies 35:8,10 copy 9:15 10:24 19:23 23:13 55:12 corner 77:23 80:22 128:9 Corporation 38:12,14 correct 10:8 11:2 12:19 15:11 17:22 18:10 19:9 23:8 25:18,24 26:12 27:13,19 30:2 31:22,24 32:1,8 33:9,16 34:5,12 35:5,9 36:6,13 38:1 38:13 39:2,15 39:22,23 40:13 40:14 41:20 42:3,22,23 44:2,3 45:16 46:23 49:11,20 51:3,4 52:14 54:20 55:10,18 56:14 57:3	60:5,17 63:7 63:13 64:16 65:9,13,14 66:13,14,16,21 68:2,3,5,6,7,8 68:20,21 69:20 69:21,23 70:7 70:8,9,10,17 70:18,22 71:3 72:12,18 74:4 74:10,16,17,22 74:24 76:16,17 77:15 78:9,11 78:17,18,20,21 79:9 80:20 82:7,8 86:7 88:13,14,16,17 88:19,22,24 89:1,6,7,10,24 91:16,21,22 92:1,6 94:2,3,7 94:13,14 95:15 95:16,19 96:17 96:19,24 97:7 97:8,10,17,18 97:21 98:1 100:13,16,17 101:1,2 102:22 103:24 104:6,7 104:11,14,20 105:18,22 106:5,6,22 107:1,12,13,23 109:11,12,14 110:2,9,10,23 110:24 111:6 111:11,12,14 112:12,13 113:8,9,17,18 114:1,15,22,23 115:1,2,8,11 115:14,15,18 115:24 116:7 116:16,23,24 118:22,23 119:3,4,10,19 119:20 120:5	121:5,21,22 122:10 123:6,8 123:12 124:1 125:18,19 126:12,24 128:11,17 129:9,10,13,16 129:23 130:13 131:1,2,3 132:1,2,9 133:2,6,7,14 133:18 134:18 134:19,22,23 135:1,2 136:13 137:3,4,13,17 137:21 138:17 138:18 139:4 140:3 141:14 141:15 142:10 142:16,17,22 144:1 146:4 147:8 corrections 146:5 correctly 18:14 53:22 68:16 97:13 115:3,4 124:16 139:11 corresponded 20:14 correspondence 10:11 20:9 counsel 3:5 54:4 54:13 112:12 140:24 141:8 142:7,23 country 75:5,11 123:18,19 COUNTY 147:3 course 5:3,3,5 16:7 18:16 21:7 30:10 80:11 127:3 128:15,15 129:1,2,8,11 129:12,15 130:3,22 131:3	131:6,7,9,12 courses 12:6 15:12,13 18:24 127:13,15 128:24 129:15 130:9 court 1:1 49:1,2 69:7 147:11 cover 17:17 26:1 29:17,21 covers 29:13 cream 38:3,4,4 create 76:8 110:4 111:21 112:19 created 22:12 103:12 107:12 credentialed 126:9 credentialing 126:7,18 136:15,20 141:4 criteria 96:23 CROW 2:9 cure 101:4,8 113:1 cured 101:7 109:7 110:8 111:11 current 9:16 57:5 88:10 89:22 143:11 curriculum 4:7 4:11 7:12 9:16 9:23 cut 84:7,9,12,13 84:17,17,19,20 84:24 85:1,5,5 85:13,15 90:7 90:11,12,15,16 90:18,23 91:10 91:11,16,16 CV 10:4,5 24:1 24:2 30:24 31:7 32:2 53:22	cystocele 101:23 cystoscopy 65:12 66:1 Cytec 38:12,14 38:15,18,22 40:6 45:9 Cytec-Hologic 45:10 <hr/> D D 7:2 Dan 78:14 data 11:12 22:8 30:23 57:22,24 83:16 86:17,18 86:19 105:24 111:5 122:9 144:5,11,15,16 date 23:19 24:7 24:17 49:15 70:14 132:23 133:5 134:5 146:8 dated 67:18 75:23 dates 44:12 133:2 day 123:22,23 124:2 125:5 127:20 128:1 131:17 132:4 135:15 136:12 146:15 147:13 days 122:21 123:4 127:15 127:18 Dayton 89:16 De 78:15 deal 36:17 dealing 34:19 dealt 37:21 December 72:8 81:6,7,8 decide 90:5 141:2 142:9,13 decided 131:15 deciding 84:16
---	---	---	---	--

Michael Karram, M.D.

Page 153

decision 83:11 83:12 126:6,7 126:8	109:15 124:10 depends 99:16 106:19 126:1	53:13,15 development 51:17	6:4 12:15 15:1 15:4,7 18:9 19:20 20:17	131:5,20 132:10 134:4 134:13,15
decision-maki... 60:8 84:15	DEPONENT 146:1	device 23:11 39:21 45:7	24:20 26:3,15 26:24 29:20	135:6 136:16 137:9,12
deck 79:7,24 107:8	deposed 24:24 25:2 47:6 48:1 49:8,9	51:13 65:24 82:19 84:16 86:12 88:18	30:15 34:17,23 39:20 40:2 41:22 42:5,18	138:19 139:3,5 139:14 140:4,8 140:17,22
decks 107:7	deposes 7:22	89:8,9 91:7,19 91:21 92:8	43:15 44:19 45:1 46:17	143:16 144:8 144:14 145:1
decree 70:10,12 70:16	deposition 1:12 2:1 3:6,10,14	93:11,12 125:17 127:4	50:12 51:10,14 51:22 52:22	discern 81:23 discuss 35:23
deem 120:20	3:15,16 4:1,4 7:4 9:6 10:9	130:8 144:7,13	53:9 54:14 57:11 58:16,23	41:8,9 42:7 95:17,21
defendant 46:8 46:24 68:7	11:17 13:3,4 13:15,19 14:9	devices 50:20,24 51:18,21 90:19	60:6,22 61:22 64:22 65:4,10	118:21 136:19 139:19
Defendants 2:18 20:12 69:10	26:7,9,18 45:17 47:24	119:2,10 120:16,22	65:17,21 66:2 69:24 71:4	discussed 21:1 26:14 42:11
Defendants' 13:12,16	49:16 53:19 145:5 147:7,8	125:23 126:15 127:8 129:18	72:13,24 73:2 74:23 75:9	56:5 66:6 76:13 94:17
defense 8:20 47:9 48:7,20 49:21	depositions 11:15 13:14 56:5 138:17	129:19 diagram 62:8,20 62:22 113:15	76:5 77:1,12 78:10 79:1,13	95:14 136:23 138:15
deficiency 60:14 61:12,19	deps@golkow... 1:24	diagrams 62:3 62:10,13	80:19 81:21 82:16,20,24	discusses 43:24 discussing 29:6
define 119:13	dermatologic 33:2	didactic 125:14	83:4,13,18 84:21 85:6	50:3 88:5 91:15 128:24
defined 106:19 147:11	describe 10:2 15:8 29:4	difference 16:1 53:7,11 63:15	86:16 87:12 89:11 90:9,21	136:4,4 discussion 55:23
definition 109:15 120:11	45:22 99:20 101:4 120:23	84:11 85:4 87:9 91:9	91:2,12,17 92:3,22 93:3	121:14 122:21 123:1,10
degree 117:15 117:21 118:14	121:2 123:23 124:2	99:14 122:6 142:9	94:20 95:11 97:11,15,22	127:19 140:14 discussions
delaying 73:5	described 14:21 42:11 50:10	differences 83:17 84:2,6 91:15	99:6 102:5,8 102:13,17	55:24 56:3 disjunctives
delivery 46:4,21	65:3,5 90:24 description 4:3 5:2 120:7	different 16:7 17:21 37:22	103:2,14,20 104:15 107:16	115:3 distinction
demonstrate 22:8 84:23 126:22	design 12:20 51:21	41:14 42:24 62:17 76:13	107:22 113:3 113:10 114:2	43:12 distinguished
denied 74:2	designed 51:24 142:13	84:24 90:22 91:4 92:8,9	114:16 115:9 115:19 116:11	108:10 distinguishing
Dentists 68:1,11 71:10	designing 121:17	100:7,8 101:6 101:8 112:1	116:20 117:18 118:19 119:11	105:1 District 1:1,1,5
Denver 2:5 133:11	detail 26:14 76:4 124:2	135:8,18,24 144:21	119:24 120:18 120:24 121:12	69:7,7 division 1:2
deny 73:8	determine 144:6	dinner 123:2,2,5 123:11 127:19	122:4 125:9,13 125:24 126:16	40:19 67:23 69:8
departed 127:20	developing	DIPAOLA 2:14	127:1,9 130:4	doctor 8:5 10:23
department 66:9 67:20 69:22 72:7 73:12,22 107:18 108:1				
depending				

Michael Karram, M.D.

Page 154

20:24 23:20	Doug 54:7,11	134:2,6,7	73:5,8 78:13	erosion 99:9,15
27:14 40:23	55:3,9	ed 12:5 16:7	78:14,23 79:2	99:18,18,22,23
49:23 55:12	DOUGLAS	17:6 19:6,7	emails 12:23	100:4
61:24 66:4	2:14	43:7 79:3,8	20:9 72:16	Errata 146:6
67:14,16 88:5	douglas.dipao...	80:3,10,14	employed 34:20	error 106:18
96:11 107:9	2:17	124:6 127:6	147:10	errors 109:13
108:2 109:6	Dr 4:4 7:5 9:7	edges 90:15,19	employee	especially 93:20
110:19,20	13:3,7,21 26:9	educated 136:9	138:17	ESQUIRE 2:4,8
113:15 116:13	28:3 68:11,12	education 15:16	employees 11:16	2:9,14
117:1,14,20	68:12 72:9,9	16:21 17:18	20:11,15 21:3	essence 30:14
120:14 121:6	78:16 128:21	18:18,19,24	70:6 74:7	essentially 95:10
125:20 128:7	140:23	21:6,12 22:10	138:20	136:6 141:24
132:17 134:9	drafting 51:9	43:14 44:6	employers 70:5	estimate 18:2
136:2 143:20	136:24 137:1	55:13 107:4,6	74:6	19:2
144:23	137:11	112:4 130:12	employment	estradiol 31:10
doctors 41:12	drive 103:1	effect 3:16 86:17	32:3,3 34:6	31:13
66:19,20 68:18	driver 92:24	86:18,20	36:11 44:1	estrogen 38:3,4
89:15 103:15	93:9	effective 60:5	endeavors 15:24	et 68:1 78:24
135:20	drivers 93:23	effectively 70:23	ended 40:18	138:10,11
document 1:7	drives 83:12	77:7	43:20 70:21	ETH.MESH
4:8 7:15 9:6	drove 76:19	effects 73:23	Endo-Surgery	78:4,4,23
67:16 70:2	Drs 69:8	efficacious	8:22	80:23 128:9
73:1 78:17,19	drug 36:15	61:11,18	engagement	ETH.MESH.0...
80:23 128:8	dry 106:12,19	effort 71:1	39:14	5:4 128:4
documentation	duly 7:21 147:4	efforts 74:19	engagements	ETH.MESH.0...
20:10	147:5	eight 99:2	39:19	5:6 130:18
documents	DVDs 10:11	133:17,21,22	England 96:12	ETH.MESH.0...
10:10,10 11:23	dyspareunia	eight-hour	enhanced 74:21	5:7 132:13
12:2,3,7,13,14	117:12,17,23	131:18,19	entire 126:3	ETH.MESH.2...
12:18 14:10,22	118:9,16	either 13:12,15	entitled 4:8,16	78:16
21:6,8 78:6,8,9		18:20 19:6	4:19,22 7:15	ETH.MESH.s...
78:23,23 79:2	E	20:15 31:5	9:6 79:7 94:16	11:23
80:22 84:23	E 7:2,2 148:1	40:8 42:7 76:3	96:6,12 105:24	Ethicon 1:3 8:22
91:15 137:7	E-v-i-s-t-a 39:8	76:12 88:12	108:12 110:12	11:16,20 12:4
138:16	earlier 13:24	101:10 129:18	110:21 113:16	12:14,16,17,23
doing 17:6 22:20	34:9 43:1,4,10	139:16	143:21	14:23 15:3,11
26:17 34:15,16	56:5 63:16	elaborate 51:15	entry 70:14	15:20,22 16:13
40:10 50:14	66:4 94:17	elasticity 85:4	epidemiology	16:16 17:1,10
58:9 72:23	136:23	electronic 20:11	52:6	17:13,17 18:6
124:18 130:7	early 23:23	electronically	equal 45:2,3	19:1,7,15,18
131:24 135:13	34:21 35:4	19:18 21:10	58:20	20:13,15 21:3
dollars 18:21	60:3	Elevate 44:9	equally 75:10	22:13,15 23:3
37:2	ease 93:24	Eli 38:24 39:3	equivalence	23:5,10,11
Donna 1:8 27:20	easier 90:14	39:13 40:6	96:24 98:9,16	29:13 30:5
Double 31:12	93:16	42:16	equivalency	34:7,16,21
doubt 20:2	East 1:17	else's 22:15	98:1,14 142:7	35:3,4,19 36:7
34:24	Easter 133:21	email 20:15 21:3	equivalent 53:1	42:21 43:2,4

Michael Karram, M.D.

Page 155

44:17,24 54:4	86:11,11 91:21	126:2 129:18	failure 97:9,14	110:22
54:5 55:7	91:23 92:4,5	137:7	109:10	feminine 31:12
57:10,14,18,20	92:14 93:4,11	experienced	fair 12:18 17:23	fewer 94:1
61:17,20 78:6	94:6	16:10 91:8	17:24 18:5	field 95:6 119:1
83:12 84:7	exactly 27:11	119:17 120:8	33:13 76:8	119:5,7,8
86:9 89:5,9	44:5 55:1	expert 13:1,11	80:17 82:18	fifth 111:1
91:14 107:10	98:15	24:11 26:22	91:1 105:16	Figure 111:4
107:12,21	exam 139:8	28:11 48:1,6,7	112:9 120:11	file 1:3 20:1
119:6,7,8	EXAMINATI...	49:19 50:4,6	129:12 136:2,7	filed 68:5,10
120:15,21	6:1,4,4,5 7:23	50:11,19,23	137:11 139:12	69:5 73:12
121:10,17	140:21 143:18	51:2,5,6,8,13	139:15 142:11	final 26:2 67:24
122:15 124:24	example 26:19	51:17,20 52:2	144:23	70:14
125:5 126:11	71:24 74:12	52:5 56:12	fairly 37:19	financially
126:15 128:14	78:12 79:6,8	82:19 94:8	familiar 76:11	147:10
129:24 130:5	90:20 114:7	100:14 109:9	79:5 98:17	find 83:17 84:11
131:24 132:21	130:2 133:8	111:6,14 117:2	far 25:20,23	122:2
138:16,17	executed 23:21	140:2 142:24	52:4	finding 96:21
141:1	Exhibit 4:3 5:2	143:4,5,6,9,24	fascial 64:1,2	finished 125:4
Ethicon's 12:20	7:6,10,13,18	expertise 71:19	101:16	firm 8:24 9:1,3
19:10 54:13	9:5,24 10:3,9	71:20	fashion 44:16	48:11,12
57:2 85:3	10:21,24 14:10	experts 13:12,16	faster 72:20	147:11
107:11 126:6	14:22 20:8	expires 146:16	fax 1:23	first 7:21 24:11
138:20	21:21 23:13	147:17	FDA 50:20	25:4,20 30:5
Ethicon-manu...	24:1,3 25:5	explain 15:8	139:21	40:23 45:23
83:8	26:22 27:14	exposure 99:1,5	February 23:23	55:2,6,14,21
Ethicon-sanct...	29:1 32:2	99:8,14,24	81:3 134:21	57:21 63:18,19
23:2	55:12 67:6,11	100:3	federal 3:8 4:14	63:19 95:13
Ethicon-spons...	67:14 75:19	extent 89:12	49:1 67:8,17	97:6 100:15
127:3	96:9,11 108:16	extrusion 99:19	69:2	108:22 109:3
Evaluation	108:18 109:5	100:2,3	federation 68:1	130:2 147:5
31:13 35:15	110:16,19,20	eye 95:7	68:10,11,14	first-time 136:6
evening 127:18	128:5,7 130:19		71:9,14,23	136:8
evenings 127:21	130:21 131:22	F	72:2,10,17	five 23:1 25:6
event 23:2 98:24	132:14,17,18	facial 63:24	74:19 95:23	81:2 86:3 88:1
132:23 133:4	136:3	fact 80:21 89:15	fee 18:15 132:5	94:12 106:3
134:5	exhibited 89:5	137:19,20	132:6,7	140:17
events 15:19	EXHIBITS 4:2	138:8	feel 93:17	flat 18:15
98:22 99:1	5:1	facts 113:10	fees 68:13 70:4	flights 127:23
evidence 52:9,12	existed 82:12	139:5	fellows 22:21,22	floor 5:3,5 56:2
52:14 53:1	expenses 18:21	faculty 122:22	93:14,21	79:15 113:21
113:11 139:6	19:8	123:10 124:11	fellowship 93:13	114:1 128:15
144:15,17	experience	124:12 125:16	felt 41:15,16	130:22
Evista 39:4,5,6	37:16 55:14	128:17 130:14	57:23 77:10	flyer 130:22
evolution 29:8	57:21 61:15	failed 59:14	95:9 96:18	Flynn 133:10,20
exact 24:16	83:16 91:5	60:14 98:1	124:21	focus 81:9
29:22,24 49:15	93:18,20 94:23	106:13,20	female 4:23	focused 83:2,5,7
58:17 85:22	95:4 114:11	109:8	20:12 110:15	focuses 82:19

Michael Karram, M.D.

Page 156

follow 4:21,22 108:15 110:13 110:21 follow-up 105:24 143:20 follow-ups 14:6 109:20 followed 125:15 following 70:14 73:23 follows 7:22 force 3:16 Ford-Cochrane 82:10 foregoing 146:3 147:8 form 12:15 15:1 15:4 18:9 19:20 20:17 24:20 26:3,15 26:24 29:20 30:15 34:17,23 39:20 40:2 41:22 42:5,18 43:15 44:19 45:1 46:17 50:12 51:10,14 51:22 52:22 53:9 54:14 57:11 58:16,23 60:6,22 61:22 64:22 65:4,10 65:17,21 66:2 69:24 71:4 74:23 75:9 76:5 77:1,12 78:10 79:1,13 80:5,19 81:21 82:16,20 83:13 84:21 85:6 86:16 87:12 89:11 90:9,21 91:2,12 92:3 92:22 93:3 94:20 95:11 97:11,15,22 99:6 102:5,8	103:2,14,20 104:15 107:16 107:22 113:3 113:10 114:2 114:16 115:9 115:19 117:18 118:19 119:11 119:24 120:18 121:12 122:4 125:9,24 126:16 127:1 130:4 131:20 135:6 136:16 137:9,12 138:5 138:13 139:14 140:4,8 141:6 142:2,21 143:8 143:14 144:8 144:14 146:5 formal 30:10 format 112:2 forth 141:11 found 66:9 89:15 95:1 142:18 foundation 79:1 four 17:7,7 25:6 37:2 45:21 59:3 66:6 81:2 81:5 86:3 127:4 133:21 134:24 135:4 135:18 136:17 four-year 37:3 fourth 1:17 49:16 133:10 frame 39:24 81:2,9,11,15 81:19 133:1 137:3 Francisco 35:22 FRANKLIN 147:3 frayed 90:20,22 free 4:22 74:2 110:13 Friday 18:16	122:21 123:5,9 127:18 front 27:15 75:20 Frost 1:16 full 89:4 123:23 131:17 full-day 131:6,7 full-length 86:8 86:9,23 87:3 88:15 89:23 90:2 91:24 funded 23:5,11 further 6:5 100:11 143:18 <hr/> G G 7:2 Gamble 36:12 36:20 40:12 41:6,19,20 42:3 general 4:5,12 7:8 10:19 27:7 27:10 28:12,16 29:1 141:12 generated 100:18 getting 111:3 gist 70:23 give 24:4 41:15 57:12 58:6 126:11 given 22:24 56:6 106:24 107:6 112:17 122:8 122:18 128:13 146:4 147:7,8 gives 53:12 103:9 giving 22:21 37:18 80:10 go 9:21 10:15 16:5 18:21 36:9 67:5 93:8 95:17 96:3 107:17 114:18	118:21 123:17 124:18 125:13 125:22 133:8 135:14,16 136:19 138:1,4 139:6 144:15 go-to 58:17,19 goes 34:11 70:2 73:24 74:6 94:12 141:16 going 23:24 26:8 53:21 77:17 89:14 93:17 108:18 110:18 114:13 123:3 130:21 132:16 140:16,23 145:1 gold 143:11 GOLKOW 1:23 good 8:2 30:18 107:9 GOODWIN 1:5 Gotcha 105:19 gotten 70:24 Government 79:16 grab 10:15 graph 141:24 graphs 141:18 great 1:17 140:19 groin 86:20 87:14 89:5 group 32:12,15 32:19 41:12 71:22 95:23 99:17 135:8 group's 72:10 groups 72:9 96:23 guess 86:4 87:19 104:21 111:18 guy 125:5 guys 133:23 Gynecare 35:15 36:7 79:14	gynecologist 119:17 120:8 gynecologists 36:17 gynecology 8:8 32:17 46:1 62:11 Gynemesh 79:7 79:14,24 <hr/> H H-o-l-o-g-i-c 45:9 half 94:12 135:15 136:12 half-day 129:12 129:15 131:3 hall 124:4 hand 23:24 108:18 110:18 130:21 132:16 147:13 handed 67:16 128:8 132:17 handing 10:23 75:18 110:19 hands 58:5 84:19 97:16 Hang 62:23 happened 72:15 125:8 happens 124:3 124:17 happy 129:19 130:8 hard 104:24 head 142:20,20 health 32:5 34:8 42:22 43:2 70:4 71:1 Healthcare 73:24 heard 90:24 hearsay 139:5 held 140:14 help 41:19 42:2 42:6,9,17
--	---	--	---	--

Michael Karram, M.D.

Page 157

71:20	134:24 135:5	123:9	36:18 122:22	12:16,17,23
hereinafter 7:21	135:18 136:17	inadvertent	individual 72:3	78:6,9 85:3
hereto 147:10	141:1	105:17,20	141:4	91:14 138:16
hereunto 147:12	house 84:1	inappropriate	individually	interrupt 83:21
hey 130:7	Houston 13:8	120:14,20	72:4	83:21
high 42:8	Howell 128:20	include 26:21	industry 51:13	interstate 69:13
higher 71:2 74:7	128:21	28:14,18 56:3	information	intervals 98:5,6
97:20	Humana 72:11	142:16	11:11 12:4	intrinsic 60:13
Highland 2:15	74:15	included 17:21	14:7 26:7	61:12,18
Hills 32:5,10,11	hygiene 31:12	19:5 52:20	42:10,14 53:23	introducer 92:8
32:13,14	hypermobility	115:12	76:21 96:1	100:10 104:23
Hilltop 32:21,21	60:13	including 14:10	122:8,18	introducers
32:23 33:6,8	hypermobility	14:22 20:10	informed 61:20	100:13
33:15,17,19	87:7	21:6 26:2	informs 58:21	introduction
34:1 35:18	hysterectomy	incontinence	inhibit 66:20	92:8 94:6
Hilton 103:23	48:5 56:1	4:18,20,24	initially 119:9	invasive 56:1
104:2,3,18	139:9,10,11,13	8:18 29:6,7,9	injure 104:24	64:9
Hinoul 78:24		29:11 30:6	105:12	investigator
hired 8:23 24:11	I	58:24 59:5,23	injuries 93:19	31:21 33:4
48:10	idea 134:11	61:2 62:11	injury 46:21	35:14,21 36:2
historical 101:6	138:22	83:6,9 96:8,14	48:4 104:13,19	36:3,4
137:7	identified 130:1	101:21 108:15	104:22 105:7	invitation 5:3,5
historically	identify 119:9	109:17 110:15	105:12,17,21	128:3,14
101:9	120:15	110:23 114:19	input 121:15,16	130:17
history 29:7	IFU 65:3,6	115:6,17,20	insertion 93:19	invoice 25:20
hold 50:19,23	136:21 137:6	116:9,14,18	inside-out 58:12	26:13 27:3
51:12,16 75:16	IFUs 12:22 51:9	117:3,7,11,16	86:9	invoiced 25:17
112:11	81:16 122:9	117:22 118:3,8	institution 16:4	26:11
Hologic 45:9	137:2	118:15 120:10	16:5	invoices 14:11
Holschuh 47:17	III 2:8 35:15	142:10 143:13	instruct 124:16	14:14,17 25:19
home 21:15	Impact 67:24	incorporated	124:19	25:23
hormone 38:16	implant 86:22	12:22	instructions	involved 33:1
hospital 30:12	124:14 125:17	incorrect 71:5	51:9 65:20	34:1 45:13,15
30:18 89:16	implanted 88:12	74:24 113:2,6	insurance 71:1	46:3,20 66:5,8
90:4,6 126:8	127:3 143:5,7	113:7	71:18,24 72:3	67:2 71:12
126:22	implanting 91:7	incorrectly	74:1	75:12
hospital's 141:4	imply 141:22	124:17	insureds 68:14	involving 46:1
hotel 129:8	implying 144:22	increase 61:5	insurers 70:4	66:9 75:13
131:9	important	68:13 110:7	intentional	ISD 60:16 61:1
hour 28:22	119:21	111:13 113:1	111:17	issue 49:4
33:23,23	impress 124:22	increases 72:22	intercourse	issued 28:11
hourly 28:21	impression	INDEX 4:2 5:1	138:24	29:18,21 35:2
33:20,21 132:3	89:13	6:1	interested 119:2	issues 16:10
hours 25:15	improved	indicating 49:5	147:10	22:8 29:9
27:12 28:14,18	106:13,20	77:20	interesting	34:19 37:21
54:17 132:8	109:7	indication 55:24	104:21	41:13 46:12
133:17,21	in-depth 122:21	indications	internal 12:13	141:14

Michael Karram, M.D.

Page 158

Italian 83:23	kickoff 78:15	52:17 72:9	40:7 42:16	121:3 129:6
item 42:20	kidding 134:15	laser 84:7,12,17	limited 104:5	133:9
<hr/> J <hr/>	Kirk 1:21 147:4	84:19 85:1,5	line 43:24 64:5	looked 50:10,13
J 2:4,14	147:15	85:13 90:7,11	70:1 133:10	53:23,24 77:5
J&J 8:22	Kirkpatrick 1:9	90:23 91:11,15	148:3	79:4,11 82:2,4
James 2:8 68:12	28:5	law 8:24 9:1,3	list 4:9 7:15 11:3	82:5 90:22
69:9	knew 14:1 126:2	48:11	11:6 12:8,10	95:24 138:16
james.lampki...	know 13:21 20:7	lawsuit 46:4,6	31:1 35:13	looking 33:14
2:11	21:20 22:17,24	66:8,18 68:4,7	40:11 76:7,8	50:7 53:13,16
January 81:4,6	24:16 25:16	lawsuits 66:5	114:24 115:13	55:4,4 57:22
81:7,8	27:9,11 31:17	67:2	133:8 140:11	79:15 102:19
job 37:13	34:16 46:13	layout 111:5	listed 27:18 31:3	104:9,17 108:3
Joe 8:11	47:13,15 48:12	lead 95:18 96:14	31:18 32:2	131:22
John 47:17	48:13,14,17	leading 136:24	35:21 45:14	looks 90:13 91:4
join 71:11	49:1,3,15	leak 87:6	80:14 81:24	111:16 113:1
joined 32:10	55:20 79:12,16	learn 130:9	94:21	loose 64:18,20
71:13	85:17 95:3	136:9	lists 37:5 132:21	loosely 64:24
JOSEPH 1:5 2:4	98:14,15,18	learned 16:9	literature 61:14	loss 91:5,10
journal 30:20,22	108:8 112:3,6	94:22	75:23	lot 32:24 37:20
31:24 95:4	112:7 113:24	learning 16:9	litigation 1:5	37:21 50:17,18
96:12	114:13 125:8	leave 64:23,24	13:2 24:12	78:4 94:23
journals 11:11	126:2,3 133:23	124:20	little 61:7,8	loud 84:1
31:2,11 95:5	133:24 134:1,1	lecture 112:17	84:20 124:2	lower 87:6 99:7
judge 1:5 144:13	134:14 137:18	124:4,5	135:8	lying 140:7
judgment 67:24	137:20 138:8	lectures 11:13	LLC 1:16	<hr/> M <hr/>
70:14	138:20 139:1	112:18	LLP 2:4,15	M.D 1:12 2:1,14
June 68:5,9 69:6	139:10	left 68:23 77:23	lobby 129:8	3:7 4:1,6,7,11
Justice 66:9	knowingly	leg/groin 118:4	131:9	4:13 6:3 7:9,13
67:20 69:22	120:21	118:10,17	location 133:4	7:20 9:24
72:7 73:13,22	knowledge	legal 34:18	long 8:9 17:2	10:20 146:8
jzonies@rpla...	37:15 109:20	46:13 71:11,18	25:10 26:18	147:5
2:6	114:14	71:19 107:17	34:14 54:16	main 56:21
<hr/> K <hr/>	knowledgeable	108:1	87:17,20,21	94:17
Karram 1:12	119:18 120:9	length 89:4	131:12	major 120:3,10
2:1 3:7 4:1,4,6	known 96:15	let's 23:22 25:14	Long-Term	majority 60:18
4:7,11,13 6:3	Kriz 1:10 28:7	59:8 81:4	4:20 105:24	82:3 95:12
7:5,9,12,20 8:4	Kuuva 104:8	letters 71:24	108:15	123:16
9:7,23 10:20	<hr/> L <hr/>	72:2	longer 127:13	making 83:11
62:16 68:12	lab 123:24 124:9	Leval 78:15	look 14:9 20:3,6	107:19
69:9 72:9	125:15,21	level 52:8,12,13	20:8 21:5,17	Malignant
140:23 146:8	133:9,14	53:1 125:21	23:16 52:15,17	143:21
147:5	135:17	LIABILITY 1:4	67:20 68:4,22	malpractice
keep 73:5 77:17	lack 12:13	license 75:15	73:11 78:2,13	46:6,22 66:24
Kelly 62:5	lady 46:2	lies 141:4	79:12,23 80:15	manage 90:6
key 77:3	LAMPKIN 2:8	ligament 63:20	97:2 98:24	management
	large 32:12,14	63:22	108:3,9,21	29:8 119:18
		Lilly 39:1,3,13	109:5 111:4	

Michael Karram, M.D.

Page 159

120:9 122:24 manual 112:17 March 1:13 3:1 23:23 57:7 72:8 145:4 Margaret 1:9 28:5 margin 98:9,16 mark 9:21 22:18 22:19 67:5 103:7 128:7 marked 7:5,9,13 7:17 9:5,24 10:3,20,23 11:23 23:13,24 67:11,14 96:9 108:16 110:16 128:4 130:18 132:13,16,18 market 39:11 41:17,20 42:3 42:9,17 57:7 88:24 89:14,19 91:21,23 92:18 marketing 41:8 41:9 42:11,13 50:24 marking 96:11 Marshall-Mar... 62:24 Massey 1:8 Massey's 27:21 Master 1:3 material 11:10 12:5 materials 4:9 7:16 10:12 11:8,22 14:5 21:7 26:9 75:19,22 77:18 77:24 94:18 107:11,15,21 122:16 127:16 144:1 matter 8:12 23:14 52:19 80:21 132:8	MDL 1:4 4:9 7:17 mean 41:9 42:13 52:16,17 56:20 60:24 64:20 98:2,4 111:16 119:6 120:4 122:12 126:1 127:22 meaning 77:2 means 98:15 meant 43:4 113:4 121:10 mechanical 90:16 mechanically 84:9,13,17,20 84:24 85:5,15 90:12,18 91:10 91:16 medical 8:5 39:21 40:12 41:5,19 42:10 42:14 44:2 45:7 46:6,22 49:23 50:20,24 51:13,17,21 66:24 67:3 75:15,23 76:14 117:15,21 118:14 144:7 144:13 medication 39:10 medications 41:14 medicine 8:9 96:12 meet 41:7,11 54:4,10,13 96:23 124:4 meeting 36:9 55:17,18 78:15 meetings 35:22 76:14 member 40:12 41:6,18 72:10	124:12 members 68:13 68:14 71:14,15 124:11 130:14 memoranda 20:9 memory 33:22 135:3 menopausal 31:10 merged 40:9 Merit 147:4 mesh 20:12 44:15 55:7 56:3 59:13,14 79:14 83:12,12 84:3,3,12,13 84:20,20,24 85:1,5 90:12 90:12 91:10,11 91:16,16 99:1 99:8,9 100:9 102:11 114:20 115:7,13,17,21 116:9,15,19,21 117:3,7,11,16 117:22 118:3,6 118:9,15 140:13 142:14 142:16 143:7 143:22 meshes 102:6 met 40:23 54:15 54:19,21 55:2 55:9 72:3 133:24 134:3 meta-analysis 52:10,13,20,24 Metherd 68:12 69:8 methods 37:22 98:8 METHVIN 2:9 Michael 1:12 2:1 3:6 4:1,4,6 4:7,11,13 6:3 7:5,9,12,20 8:4	9:7,23 10:20 68:11 69:9 146:8 147:5 midurethra 59:16 midurethral 4:17 95:24 96:7,13 142:14 143:11 Mike 133:24 MILES 2:9 mind 16:1 29:17 MiniArc 44:8 58:4,5 minimally 56:1 64:9 minus 98:10 141:1 minute 111:1 minutes 88:1 140:15 141:1 minutes' 140:17 Miranda 1:10 28:9 mischaracteri... 115:10 116:11 misrepresent 139:17 Mississippi 2:16 misstates 107:22 144:14 mistake 106:15 mixed 61:1 mixing 92:12 MMK 62:20,23 101:11 Monarc 44:8 58:11,20,22 85:19 87:20 88:13,15 money 46:14 73:4 Montgomery 2:10 months 10:6,7 25:6 41:1 50:13 81:2,4,5	110:8,9 111:8 111:9 113:2 136:24 141:23 142:1,1 morning 3:1 8:2 18:17 40:24 54:19 move 93:10 116:1 moving 72:20 multiple 59:13 62:17 127:8 <hr/> N <hr/> N 7:2 Nambiar-Coc... 82:14 name 8:3,11 37:12 47:17,18 47:23 48:12,14 133:4 134:10 named 46:8,9 narrowing 118:4,10,17 nature 14:12 68:23 NDP 78:14 nearly 102:15 necessarily 60:20 98:2 103:10 130:6 137:2 neck 59:16 need 59:15 72:20 88:2 needed 14:18 112:11 needle 101:11 negotiate 71:17 71:20 neighborhood 17:3,4 18:15 18:20 33:23 37:2 neurologic 46:12 never 14:19,20
---	---	---	--	---

Michael Karram, M.D.

Page 160

31:23 57:16	O 7:2	126:16 127:1	offered 119:22	142:15
91:8,14 114:3	OB-GYN 68:13	130:4 131:20	offering 94:18	operative 94:1
129:21	72:9 74:3,8	135:6 136:16	offhand 48:13	opine 65:12
new 79:14 93:12	OB-GYNs 69:11	137:9,12	office 21:15 55:3	opinion 29:18
96:12 129:21	70:4 71:23	138:19 139:14	147:13	29:22 41:16
NG 78:14	Object 12:15	140:4,8 141:6	official 3:12	65:18 66:17,22
nice 123:20	15:1,4,7 18:9	142:2,21 143:8	Ogah 82:6 95:14	77:5,10,15
night 122:21	19:20 20:17	143:14 144:8	oh 20:21 24:6	78:20 80:9
123:5,9 135:10	24:20 26:3,15	144:14	55:23 109:4	86:19,19 90:14
Nilsson 104:9	26:24 29:20	objection 34:17	Ohio 1:18 69:7	99:18 117:2,12
nine 99:1	30:15 34:23	65:10 69:24	69:11 134:22	117:14,20
non-inferiority	39:20 40:2	72:13 102:13	147:2,4,13,16	118:7,13 120:1
98:18	41:22 42:5,18	116:20 120:24	okay 9:10 10:15	120:21 125:20
non-mesh	43:15 44:19	127:9 131:5	20:21 23:15	140:1,6 141:1
140:13	45:1 46:17	139:3	24:6 62:2	144:19
nonresponsive	50:12 51:10,14	obligation 70:13	67:15 73:2,16	opinions 10:13
116:2	51:22 52:22	observational	77:22 79:22	77:6 94:18
nonstop 127:23	53:9 54:14	52:20 53:1	81:10 83:16	95:10 96:19
norm 130:12,14	57:11 58:16,23	obstetrician-g...	86:1 92:11,13	137:5
Notary 3:9,11	60:6,22 61:22	37:20 69:10	93:6,8 98:11	options 137:16
3:13,15,15,17	64:22 65:4,17	obstetrics 32:17	98:18 99:7	oral 20:11 37:8
146:18 147:4	65:21 66:2	45:24 46:1	103:8 108:20	37:11
147:16	71:4 72:24	obturator 58:19	109:4 112:8	organ 114:19
notation 109:23	74:23 75:9	59:2 60:10,11	123:9 129:4	115:6
noted 65:19	76:5 77:1,12	60:15,17,21	130:23 132:19	organization
146:6	78:10 79:1,13	61:17 82:23	133:15	71:8
notes 10:11	80:19 81:21	83:3 85:9,12	okayed 12:9,10	Organon 37:6
notice 3:10 4:4	82:16,20,24	85:18,23,24	old 45:10 100:23	37:13 40:6
7:4 9:6 10:9	83:4,13 84:21	86:2,6,14,22	Olson 106:7,7	original 92:7,15
14:9 21:23	85:6 86:16	87:3,10,16	108:4	92:17 93:2,10
139:22	87:12 89:11	88:6,11,18	once 37:14	94:4 113:5
noticed 24:19	90:9,21 91:2	89:4,9 90:2,5,8	86:11 89:17	141:16
90:19	91:12 92:3,22	97:21 101:14	127:4	ors 115:4
notices 4:15	93:3 94:20	104:10 106:5	one-day 129:1	osteoporosis
67:10,18	95:11 97:11,15	127:11	ones 17:21 24:23	36:15,18 39:10
number 11:23	97:22 99:6	obturators	25:2 31:7,15	41:13,13,24
11:24 27:18	102:5,8,17	85:10 87:20	33:18 76:22	42:8,8
39:18 52:15,17	103:2,14,20	97:14	80:14 81:23,24	Ostergard 13:21
56:5 62:3	104:15 107:16	Obviously 53:22	94:21 95:2,9	Ostergard's
66:19 80:23	107:22 113:3	occasion 59:9,11	127:17 130:15	13:3,15,18
110:8 111:10	113:10 114:2	occur 47:11	135:11	26:9,18
114:5 121:20	114:16 115:9	123:13	ongoing 47:4	outcome 46:11
numbered 79:20	115:19 116:11	occurring	open 74:3 105:3	46:13 47:8
numbers 62:1	117:18 118:19	140:12	105:6	48:17,19
141:17,19	119:11,24	occurs 123:11	operate 43:5	outcomes 78:14
	120:18 121:12	odds 53:7,15	operation 109:8	89:4 118:1
O	122:4 125:9,24	Odenkirk 72:17	operations	outpatient 64:9

Michael Karram, M.D.

Page 161

outside 67:3 123:16 outside-in 58:11 87:21 overactive 61:3 61:5 overlapped 106:21 overlaps 108:10 oversights 41:3 41:4	138:23 paper 96:18,21 97:2 111:9 113:5 141:13 papers 76:15,18 76:24 77:3,9 77:14 paragraph 68:5 68:23 73:11,17 73:21,24 108:22 109:2,3 parallax 141:13 141:14 paravaginal 63:6 Parkway 2:15 part 14:19 30:24 31:5 32:12,18 33:7 41:18 42:2 62:14 72:6 77:16 111:22 120:4 122:5 123:1 participant 125:16 participants 122:22 123:10 124:10,13 participate 34:4 129:14 participated 69:11 118:22 127:7,17 participating 75:6 particle 91:5,10 particular 57:9 58:14 80:8 84:16 87:1,2 94:2 123:17 141:3 parties 3:6 parts 75:4 102:23 party 147:10 pass 63:21 pathology 51:5	51:7 patient 24:14 25:1 41:17 57:13 58:6 59:1,12,13 60:16,19 81:12 87:2,2 88:10 136:21 137:2,6 138:2,6 139:7 patients 24:18 24:21,23 26:7 41:23,24 42:6 53:20 74:13 86:18 99:2,4 109:6 137:15 137:19,20,24 139:23 Patterson 1:10 28:9 Paula 1:10 28:7 pay 19:8 135:5 payment 133:6 peer 31:15 peer-reviewed 30:19 31:2,4 31:18,24 pelvic 1:4 5:3,5 20:12 56:2 62:10 79:15 113:21 114:1,4 114:5,8,10,11 114:12,15,19 115:6,13,18,21 116:10,15,19 117:4,8 118:9 118:16 128:14 130:22 people 41:7 43:8 73:5 100:4 124:24 127:20 percent 56:23 56:24 97:5,5 97:10 99:4 101:10,11,13 101:15,16 106:12,13,13 106:14 108:8	109:11,11 percentage 57:9 57:12 98:10 percentages 106:12 108:7 Pereyra 101:12 perforate 100:9 100:10 perforation 65:9 100:6,8 perforations 94:2 100:12 perform 35:20 101:20,22 126:9 performed 56:13 63:8 65:13 101:17 101:19 performing 16:11 71:3 Perigee 44:8 period 21:2 37:3 40:5 70:13 permanent 105:2 114:21 115:8,13,18,21 116:10,15,19 117:4,8,12,17 117:23 118:3,9 118:16 138:23 permitted 107:14,20 persistent 72:21 person 54:21 125:22,22 135:21 personal 114:14 personally 114:3 126:22 Pfizer 37:24 38:2,8 40:6 ph 917.591.5672 1:23 pharmaceutical 30:23 39:21 40:8,18 45:7	Pharmaceutic... 37:6,24 phone 54:22 55:1,2 100:19 100:21 102:20 103:19 photo 63:1,15 63:17,18,19,20 63:24 64:14 103:18 photograph 100:18 102:20 photographs 100:15 111:23 phrase 105:16 113:20 physical 124:23 physically 91:4 physician 16:9 42:1 69:9 125:8 126:23 127:2 129:16 physicians 32:15 36:17 42:7 61:20 65:24 68:1,11 69:10 70:24 71:9,9,11,12 74:19 107:1 122:8,15 126:11 129:17 129:24 133:13 133:14 pick 129:7 131:8 picture 63:12,24 100:20 pictures 22:2 piece 79:8 80:3 pieces 91:6 pill 37:8,9,11,14 37:16 place 30:17 123:17 147:9 places 123:20 127:23 plaintiff 47:15 48:14 69:5,19
--	---	--	---	--

Michael Karram, M.D.

Page 162

140:24	practice 32:5,9	present 2:20	25:14 34:9	59:13 85:9,12
plaintiff's 47:10	32:16 56:18	32:8 34:7,13	40:20 52:11	86:9 87:21
47:18 141:8	59:23 88:10,19	36:10 38:12	56:23 59:3	89:23 124:5
142:7	89:22 99:5,8	40:11 42:20	61:6 80:4,10	production
Plaintiffs 2:13	120:3,11 138:3	43:1,13,17	82:3 86:3	77:18,24
3:7 8:12	138:4	44:12,13 56:15	89:20 90:16	128:13
Plaintiffs' 13:12	practices 51:13	100:24	95:2 103:21	products 1:4
13:15 142:23	71:13 72:4	presentation	112:1 126:5	12:4,21 29:12
please 8:2 9:20	practicing 8:9	22:20,23,24	139:15	29:13,15,16
9:21 10:2 29:4	69:11	35:23,24 36:8	problem 41:17	30:6 44:7,15
75:18 83:21	Pramudji 13:8	60:20 102:19	53:13,15,16	57:2,6,10 59:6
plexus 46:21	preceding	102:21 103:1,4	problems 118:5	81:17 84:8,9
49:14 56:9	142:15	103:5,6,8,11	118:11,18	119:22 122:9
plication 62:5	preceptor 18:7	106:24 111:23	procedure 3:8	130:10
plus 18:21 98:9	34:8 42:21	112:1 125:15	8:18 11:12	prof 12:5 16:7
point 80:6 84:15	43:8 44:1	presentations	16:11 60:5,10	17:6 19:6,7
87:6 105:6,20	133:6	21:11 22:7	60:11 61:5	43:7 79:3,8
107:9 134:4	preceptors	55:20 103:12	63:8 64:9,10	80:3,10,14
points 98:10	132:21	103:15	64:12 93:16	124:6 127:6
140:23	preceptorship	presented 12:10	94:1 104:23	professional
polypropylene	16:8,12 19:6	35:21 55:22	109:18 124:14	15:16 16:20
91:6	30:14 134:21	103:12,16	126:9 140:13	17:18 18:18,19
POP 102:11	135:5	107:11 112:22	141:3	18:24 21:6,12
population 42:4	preceptorships	121:20	procedures	22:10 43:13
58:6,8 65:24	15:14 16:2,3	presenter 55:17	53:14 59:4	44:5 107:3,6
104:3	16:14,17 17:6	121:24	65:13,16 71:2	112:4 130:12
portion 27:12	17:10,14 18:19	presenting	74:15,20 75:5	Professor 78:15
120:3,10 121:3	19:4,14 43:7	104:13	93:15 101:8	program 18:14
123:5,6,7	43:14 44:6	presents 88:10	102:11 109:19	36:17 43:22
PORTIS 2:9	45:6 135:4,19	pressures 87:6	109:21 126:4	93:13 101:6
positions 142:14	predetermined	presume 102:21	130:7	121:14 122:8
possession 21:8	98:9,16	pretty 25:21	proceed 121:15	135:9
possible 140:11	preference	prevalent 96:2	Proceedings	programs 15:17
Possibly 35:12	58:14	previa 46:2	68:24	40:10 112:23
post-menopau...	Premarin 38:3	previous 11:11	process 60:8	121:13,18,21
38:5	preparation	59:2 60:14	118:24	121:23 122:3,6
poster 35:24	11:16 80:16	95:1 126:1	Procter 36:12	135:18 138:9
potential 119:9	81:1,15,19	prices 74:7,20	36:20 40:12	project 35:18
143:21	prepare 11:6	primary 35:13	41:6,19,20	prolapse 102:3,6
potentially	25:4 53:18	36:1,2,4 92:24	42:3	114:19 115:6
114:20 115:7	76:20,21	93:9,23 109:18	proctorships	Prolift 13:7 14:2
116:9 117:3	prepared 4:5,12	109:19,20	135:13	Prolift/SECUR
PowerPoint	7:8 8:17 10:19	prior 17:9 50:16	produced	133:9
21:11	54:2	54:21 59:21	132:20	proof 3:12
PowerPoints	preparing 81:11	private 32:5,9	product 20:12	proper 126:23
21:7	presence 3:11	probably 17:3	35:19 38:9,19	properly 139:1
Pozner 2:4,21	147:7	19:3 21:16	41:17 57:8	Proposed 67:23

Michael Karram, M.D.

Page 163

proposition 97:19	119:13,16,23 120:4,7,11,15	reacts 143:7	111:20	relates 1:7 29:9
propounded 146:5	120:22 125:22	read 54:1 68:15	recruit 71:11	relationship 49:14 53:16
protocol 109:6	126:5 130:2	76:12 95:5	recurrent 4:20	relative 53:7,12
proves 144:5,11	141:2 147:5	115:5 138:17	108:14 109:17	relevance 69:24
provide 71:1	question 20:24	146:3	109:19	relevant 96:2
76:10 112:12	45:12 51:15	reading 73:1	reduced 147:7	reliance 4:8 7:15
126:18 136:15	66:24 72:24	80:2 95:6,7	reference 94:17	11:3,6,22 12:8
provided 10:12	104:16,21,22	115:3	REFERENCED	75:19,22
22:13 24:1	112:3 116:3,5	real 99:21 107:8	4:9 7:16	relied 96:19
26:10 27:1	117:19	111:15	References 94:9	rely 80:16 94:18
53:23 76:7,10	questioning	really 30:16	94:16	94:21 95:3
107:12,21	70:1 141:9	54:3 57:12	referring 99:21	relying 78:19
providing 74:13	questions 16:10	126:6 142:18	99:23 105:13	remember
PS 79:7,14,24	124:7 140:16	realm 45:11	reflected 111:13	48:16 129:5
Public 146:18	141:11 146:4	67:3	111:23	135:7,10
147:4,16	quick 127:24	reason 14:16	reflecting 20:10	139:21 141:8
publication	quite 48:9 76:11	82:9 87:1,15	reflection	142:4,23 143:2
30:22	134:8	105:1 148:5,7	128:23	renegotiate
publications	quote 72:16	148:9,11,13,15	reflective 96:18	72:11
31:4,19 33:14	quotes 72:19	148:17,19,21	reflects 97:13	rep 130:6
published 30:19	104:18	148:23	111:15 112:24	repair 1:4 62:20
30:24 31:10,12	quotes 72:19	reasonable	113:1	63:1,2,6,13,16
31:23 33:18	R	117:14,21	regard 91:19	79:15
pubofascial	R 1:5 7:2 148:1	118:14	Register 4:14	repairs 102:3,7
59:10	148:1	reasons 89:2	67:8,17 69:2	141:24
pubovaginal	R-e-z-a-p-o-u-r	90:17 93:21	Registered	Repeat 104:16
101:16	108:4	recall 56:6 66:6	147:4	replacement
pull 96:3 103:18	R-i-c-h-t-e-r	66:10 73:7,10	regular 57:17	38:16
purchase 74:3	95:18 96:15	88:6 125:11	regulations	report 4:5,9,12
purpose 16:8,12	raised 70:3	receive 19:14,17	50:20	7:8,17 8:17
68:23	ran 121:13	85:17 126:14	regurgitate	10:14,19,24
purposes 17:13	randomized	136:14 138:21	94:24	11:16 13:7,9
pursuant 3:10	52:11,21,23	recess 55:11	Reilly 2:4,21	13:10 14:3
put 12:4,7 29:5	53:2,5	88:3 113:13	reimbursed	21:23 22:14
61:7 75:16	range 32:16	recognize	75:10	23:14,17,21
105:8 109:9	81:4	134:10	reimbursement	24:2 25:5,10
112:16 122:7	rare 59:9,11	recollect 18:14	71:2 74:14	25:14 26:2
132:8 141:11	rate 28:21 97:9	recollection	75:4	27:7,10,20,23
putting 90:13	97:20 99:8	17:12 136:5	reimburseme...	28:2,12,15,16
104:18	109:10	62:12	71:21 72:1	29:1,5,12,17
Q	rates 96:22 97:4	record 8:3	relate 10:13	29:21 49:4,5
qualification	97:14 101:3,7	140:14	12:3	50:6,7 53:22
3:13	101:7 141:18	records 14:11	related 20:12	54:3 55:13
qualified 119:1	141:19	14:11 24:13	21:6 23:10	56:12 61:24
	ratio 53:8,15	53:20	36:14 44:15	63:23 76:16,19
	reached 68:18	recreated	46:4 50:20	76:21,23 77:9
			144:18 147:9	

Michael Karram, M.D.

Page 164

77:14 80:16	45:24 46:3,9	11:15,19 12:17	RMR 1:21	109:6 128:9
81:1,12,16,20	residents 30:11	12:20,23 13:1	147:15	129:7 131:8
82:1,6,19,23	93:14,20	13:3,7 50:5	role 8:13 39:13	133:16,20
83:2 94:8,15	resides 102:21	53:20,21,24	41:18 42:2,16	139:9 140:6
95:8 100:14	respective 3:6	76:3 78:9,12	room 41:12	scarring 118:4
105:16 108:2	respectively	78:17 79:10	rotation 14:1	118:10,16
109:9 111:6,14	97:6	81:23 82:14	rough 18:1 19:2	schedule 9:11,13
113:9,16	responsibility	137:10	roughly 97:10	40:4
125:14 134:20	141:2,3	reviewing 26:6,7	round 55:22,24	school 100:23
136:3,24 137:1	responsible	26:8,18 43:1	routine 65:12	scientific 11:12
137:11 140:3	138:7	55:5	RPR 1:21	61:14 81:20
141:9,12	rest 134:6,6	reviews 31:16	Rule 147:11	144:5,11
143:21	restrained 69:12	revoked 75:16	Rules 3:8	scope 102:9
Reported 1:21	restraint 74:9	Rezapour	<hr/> S <hr/>	screen 100:16
Reporter 147:4	result 98:7	106:23 108:4	S 7:2 106:8	100:20 102:20
reporting	results 58:6 64:9	108:19 109:5	safe 60:4 144:4	screenshot
147:11	64:11 94:9,16	Richter 95:18	144:11	103:22
reports 12:16	97:2	96:14	safety 144:6,13	screenshots
13:2,11 26:6	resume 35:14	Ridgeland 2:16	sales 119:6	21:24
26:23 27:2	36:1,11 40:24	right 11:1,4,24	130:1	seal 147:13
28:11	45:8	12:1,11 19:8	Samaritan	second 45:24
represent 8:11	retention 118:5	19:11 21:22	30:18	46:19,20 50:15
representation	118:11,17	29:2 34:9	San 35:22	62:23 63:20
141:12	RetroArc 44:9	35:16 37:24	satisfied 125:17	68:4,22 78:13
representative	retropublic 4:16	41:1,16 45:14	Saturday 18:17	97:6 123:22
129:7 131:8	29:14,23 30:1	49:19 62:15	123:6,7,23	section 32:3
representatives	56:21 57:1	64:18 67:18	127:19	34:6 68:15
71:16 119:1,5	58:13,17 59:22	69:3,14 75:24	save 73:4	69:13 75:22
119:6 130:1,1	60:9 61:4,19	78:2,7 79:19	saw 14:19,20	77:17 94:8,15
represented	64:15 82:19	79:19 80:13,22	80:5 93:18	97:3 98:8
141:23	86:10,12 91:19	81:2 93:6	126:2	108:22 113:16
representing	91:20 92:1,6,7	95:20 96:16	saying 111:18	113:19 118:21
72:4	92:15,17 93:1	113:24 115:4	113:20 115:22	136:3 137:14
reps 119:7,8	93:4,10,18	115:23 116:5	116:12,13	143:20 144:4
request 85:13,15	94:4 96:6,13	119:14 121:4	140:9	Secur 29:18
90:7 103:3	97:6,20 99:1	122:24 128:8	says 7:22 9:11	30:3
requested	101:1,10 104:6	128:22 129:5	26:17 32:20	see 9:11,20
102:24	106:4	132:23 133:11	34:7,13 36:1	20:22 23:22
requests 14:6	review 11:9	133:16,17,23	36:11 37:23	25:14 27:17
21:5	12:12,16 13:11	135:7,10	42:20 43:17	30:23 32:3
requirement	13:14,18 14:2	136:22	44:11 55:16	55:14 62:6
65:15,20	24:13 81:12,16	right-hand	63:1 68:9 69:5	63:18 64:6
research 32:21	81:20 82:2,6	67:21	69:15 74:5,11	67:17,21 68:24
32:22,23,23	82:10,14 122:9	rigid 59:14	77:24 78:4	73:19 77:18,23
33:13 35:18	122:17,19	risk 42:8 53:7	79:24 80:23	78:4 79:24
reserve 140:15	137:2	53:12 137:16	97:1 104:18	81:4 91:9
resident 45:23	reviewed 9:13	risks 140:7		94:10 98:8,12

Michael Karram, M.D.

Page 165

99:2,7 105:4 105:24 106:8 108:5 110:20 113:21 128:8 128:15 130:9 132:21 133:16 134:17 135:20 135:23 143:22 seen 9:5 79:11 80:21 84:23 85:3 91:14 Self-insured 74:6 sell 120:16,21 seminal 76:23 77:2 110:1 seminars 136:10 136:11 send 19:18,22 19:22 43:5 122:15 sensation 93:12 93:17 sense 18:11,23 23:20 36:23 56:17 76:11 87:23 106:14 sent 13:20 14:4 14:5 19:21 133:6 sentence 64:6 98:9 108:22 109:2 115:5 120:2 144:3 separate 16:22 separately 27:6 series 100:15 services 74:3,8 74:12 serving 119:1 session 3:1 121:3 122:10 122:20 123:4 136:5 sessions 123:22 125:1 126:11 127:7	set 121:10 132:5 132:6,7 147:12 settled 46:14 70:9 settlement 68:19 70:11 Settling 69:9 seven 32:5,10,11 32:13,14 40:20 sexual 138:23 Sharon 1:9 28:3 sharper 91:1,3 Shaver 2:21 Shea 2:21 Sheet 146:6 sheets 14:11 shelf 57:8 Sherman 68:15 69:14 74:21 shoot 103:18 short 55:11 88:3 113:13 136:11 shorter 91:24 92:4 130:3 shortly 94:9 show 98:1,6 144:17,21 showed 86:17,18 showing 63:2 64:17 85:4 101:6 127:16 shows 82:23 101:4 110:6,7 134:24 sign 3:14 19:21 138:6 Signature 145:2 signed 3:17 19:22 23:19 138:5 significant 11:23 61:2 97:24 98:3,7 significantly 74:7 109:7 similar 42:16 44:16 75:4	89:4 94:24 96:23 Similarly 118:13 simple 60:12 simultaneously 100:4 single 12:12 76:3 single-incision 58:3,4 82:15 single-specialty 32:12 sir 8:2,11 sit 18:11 31:17 143:10 sites 62:13 situation 36:19 58:10 60:23 61:10 87:5,20 125:4 situations 87:11 six 28:12,15 39:19 40:20 94:12 95:5 133:13,13 134:9,11,18 Sixteenth 2:5 sixth 79:7,23 skilled 66:1 slide 79:3,7,24 101:4,5 104:12 104:17,19 105:23 106:10 107:2,3,7,8 109:9,13,23 110:1 111:20 111:21,22 112:4,8,19,21 112:24 113:4,4 141:13 slides 22:7,9,12 22:14,15,16,16 22:19,23 107:6 124:6,6 sling 57:23 58:4 58:17,19 59:10	63:24 64:1,2 64:23 65:1,13 86:23 87:3 88:11,15 89:23 90:2 91:24 92:4 99:1 101:16 138:14 142:14 slings 4:17 29:10 56:13,18,20,20 56:21,21,22,24 57:14,15,19,20 57:21,23 58:1 58:2,4 59:14 82:15 83:5,8 83:14,15 84:3 84:4,7 88:6 95:24 96:8,13 101:13,24 102:15 143:6 143:11 144:18 Smith 78:14 Snow 2:15 9:2 25:9 53:24 snowy 123:21 sold 20:13 40:18 somebody 16:4 22:15 59:14 60:11 61:1 87:6,7 126:2 138:10 140:11 someplace 18:22 Somewhat 53:10 sorry 20:5 22:5 47:10,20 61:24 79:18 86:1 97:3 99:13 sort 75:13 126:12 sought 40:3 sounds 80:2 88:12 93:23 Southern 1:1 69:7 space 59:3 64:24 90:14	SPARC 44:9 58:12,15 speaker 34:8 36:16 42:21 43:6 44:1 speaking 39:14 107:10 spearheaded 72:10 special 37:15 specialty 8:7 specific 56:20 57:13 81:20 specifically 72:16 80:15 85:13 90:7 137:10 specifications 12:21 specified 147:9 spelled 39:7 spent 27:7,9 133:5,16 sphincter 60:14 61:12,18 spoke 39:4 138:9 spoken 15:19 114:3,15 spreadsheet 5:7 132:12,20 SS 147:2 stable 141:24 Stamey 101:12 STAMPED 5:4 standard 65:16 143:11 144:6 144:12 standpoint 61:4 71:18 93:15 stands 97:19 start 30:5 59:8 62:5 75:22 89:20 121:2 125:23 started 17:3 34:9 86:21,23
---	--	--	--	---

Michael Karram, M.D.

Page 166

92:5,14	116:8,14,18	subscribers 74:2	114:5,8,10,15	88:2 103:2
starting 59:21	117:2,6,10,15	subsequent 40:5	119:1,23	105:20 111:1
108:23	117:22 118:2,8	subset 58:8	120:15,17,22	taken 1:16 3:9
starts 64:5 94:9	118:15 120:9	116:17,22	122:13 135:8	45:17 55:11
113:20	142:10 143:12	118:7	135:14 136:6,8	88:3 113:13
state 8:2 49:2,3	strike 116:1	subsets 116:23	136:11	147:8
70:2 147:2,4	strong 52:10	substance 146:5	surgeries 59:2	talk 22:21 26:8
147:16	stronger 52:23	substandard	surgery 16:5,6	36:17 37:14,18
statement 67:24	53:4	46:15	56:1,2 59:18	38:4,6,19 41:7
113:19 137:15	strongest 52:12	success 96:22	60:14 62:11,12	41:12,24 71:17
142:11 144:10	studies 23:5,9	97:5,20 141:18	114:11,12,18	95:13 100:11
144:22	23:10 30:24	141:19	115:5,16,20	114:13
states 1:1 66:13	32:24 33:1,2,2	sued 56:10	116:8,14,18	talked 100:1
66:18 68:1,10	33:4,24 35:13	SUI 119:18	117:2,6,10,15	138:11
68:19 69:7,19	52:15,18,19,20	Suite 2:5,15	117:21 118:2,8	talking 53:21
70:15 72:7	52:21 53:1	Sunday 18:17	118:14 135:14	66:24 78:3
75:13 97:3,4	94:24 95:1,13	supervision	135:21 138:1	83:14,15 99:17
138:5	104:3 106:3	125:16	139:20	99:17 136:19
statistical 98:17	109:18	support 77:10	surgical 4:23	talks 11:13
statistics 52:3	study 31:6,9,12	77:15	59:4 101:3	38:20
53:14	31:14 34:4	supported 95:22	110:14,22	Tamera 128:20
stenotype 3:9	35:23 51:24	supposed 21:21	119:18 120:9	tampon 33:2
147:7	82:6 95:14,14	122:11	surprised 82:22	tape 4:19,23
stiffer 84:20	95:18,19,21,22	suprapubic	suture 105:2	61:8 108:13
stipulated 3:5	95:24 96:3,12	105:9	sutures 63:21	110:14,22
STIPULATI...	96:16 97:10,17	sure 10:16 15:10	105:4,8	tapes 142:14
3:4	97:18,19 98:14	16:22 23:16	switch 89:2	target 41:20
stock 89:17	98:19,21	25:21 40:19	switching 93:24	taught 15:16
stocking 89:18	100:24 103:23	45:23 48:9	sworn 7:21	18:24 133:14
stop 33:10 86:14	104:8,9 106:7	51:16 65:5	146:14 147:6	134:21
92:15,24 93:9	106:23 108:19	72:22 88:9	symptoms 61:6	teach 93:16
stopped 17:6	109:5,16,16	99:21 104:17	synopsis 62:17	teaching 15:12
34:15,16 40:10	110:1,18,20	105:8,19 107:8	synthetic 83:5,8	15:24 16:7
44:13 86:12	111:2 141:17	111:15 117:20	101:13 102:6	93:14,15,20
89:17 91:24	141:23 142:4,6	120:20	102:11 138:14	101:6 112:2,16
92:6	142:8,8,13,18	surgeon 16:11	System 1:4	112:17,23
Street 1:17 2:5	stuff 127:24	99:16 119:14	35:16	124:15 138:8
2:10	subject 52:18	119:16 120:7	Systems 44:2	teachings 94:22
stress 4:17,20,23	subjective 101:8	120:12 121:15		technique 64:18
8:18 29:6,7,8	subjectively	130:5,7 136:20	T	64:21 105:14
29:10 30:6	96:22 97:4	138:12	T 148:1	105:14 122:23
59:5,22 83:6,8	Submissions	surgeon's 22:16	T-O-M-U-S	124:23
96:8,14 101:21	79:16	surgeon-surge...	95:17 96:16	techniques
108:14 109:17	submitted 14:14	30:13,16	table 55:22,24	53:14 126:24
110:15,22	25:13,21,23	surgeons 32:18	tactile 93:12,17	136:9
114:18 115:5	Subscribed	43:5 71:9	take 4:4 7:4 9:6	TECHNOLO...
115:16,20	146:14	113:21 114:1,4	23:16 30:17	1:23

Michael Karram, M.D.

Page 167

TELECONF... 2:8,9	theoretically 105:7,11	134:15	85:10 92:19	146:4
telephone 138:21	therapies 38:17	thousand 37:2	143:10	transdermal 31:9,13 33:1
tell 22:6 25:10	therapy 143:12	three 10:6,7	today's 26:6	transition 93:22
25:13 55:1	Thermachoice 23:7 35:15	17:5 19:3,5	53:18	transobturator 4:17 56:22,24
138:10	thigh 89:5	24:18 26:22	Todd 1:16	58:9,11 61:6
telling 139:16	thing 10:14	29:14,15,16	told 103:6 125:5	96:7,13 97:7
140:10	60:13 94:24	37:2 40:24	138:24	transobturators 97:9
temporary 114:21	99:23 139:7	50:13 54:17	Tom 134:1	travel 18:21
ten 70:13,19	things 11:13,14	81:3,4,4	tomorrow 24:19	19:8,10,11
tension 4:22	15:13 17:6	124:13 127:4	24:21 26:8	traveling 43:14
61:8 90:15	33:3 95:7	136:24 140:24	50:3 53:21	treat 59:5
110:13	114:6 122:19	three-year 4:22	TOMUS 95:17	treating 59:22
tension-free 4:19 108:12	think 12:3 13:8	110:12,21	95:21 96:15	143:12
110:21	15:6 16:3,6	tie 63:21	142:4,6	treatment 4:23
tensioning 64:18	17:24 18:20	tied 63:18,19	top 63:21 67:17	29:10 61:18
64:20 65:2	19:24 24:21	ties 63:19	77:23 78:13	101:21 110:14
term 98:17	31:7,11,15	tighter 61:7,9	top-down 58:13	110:22
terminology 142:8	33:11,22 34:11	time 3:9 10:6	topics 76:24	treatments 29:6
terms 70:16	35:7 37:10,11	14:10,11 15:22	77:3	trial 47:9,11
71:20	39:17 43:12,20	17:24 21:2	TOT 87:22	48:21,23 49:10
testified 91:20	43:22 44:9	27:7,9 28:14	101:14	49:12,18 53:2
138:21	45:12 46:14	38:8,22 39:24	total 18:13	53:5 56:6
testify 8:17	47:17 48:9	40:5 48:4	25:19 139:5	trials 11:19 23:4
48:23 147:6	49:12,13 55:4	54:19 55:2,6	Tower 1:17	23:10 52:11
testifying 8:19	55:22 57:7	56:18 60:1	town 19:7 32:24	tried 57:16
49:24	59:19,20 60:1	63:10 74:13	trade 69:13	trocars 100:12
testimony 49:10	63:10 65:15	81:1,9,11,15	74:10	true 40:15 86:10
56:6 76:2	73:4 75:1,3	81:19 86:1,6	trained 30:8,9	116:8,13,18,23
130:11	83:2,5 84:10	93:19 101:17	114:4,11	117:1,6,10
testing 33:22	87:1,10,13	104:24 105:12	122:13,16	118:1 147:8
85:4	97:23 99:16,22	122:16 124:15	129:17	truth 139:16,17
testosterone 31:14	100:3,4,15	133:1,5,16	trainees 129:21	147:6,6,6
textbook 62:19	102:12 105:13	136:1 137:3	trainers 131:1	try 42:17 126:23
textbooks 11:10	107:5 111:15	138:23 144:16	training 30:13	trying 42:12
54:2 95:4	112:15,21	144:17,23	55:13 113:16	49:13 55:21
Thank 9:20	119:21 120:14	147:8	118:22 121:2	72:1 75:4,7,8
10:17 25:3	126:17 129:3	timer 130:2	121:14,18,20	124:21 139:17
83:15 88:1	133:13 134:10	times 45:20	121:23 122:3,6	139:18
144:23	134:13 136:23	127:4,5	122:8,10,20	Tuesday 3:1
Thelma 1:8	139:15,20	title 80:2	123:4,22 125:1	4:14 54:15,18
27:23	third 31:9,11,13	today 8:14 14:12	136:4,5	67:9 145:4
	47:24 64:4	14:17 18:11	trainings 123:13	turn 9:9 27:14
	thought 34:10	21:18 24:19	transcribed 3:11	75:18 79:6
	66:23 71:15	31:17 40:15	transcript 3:14	98:21 108:2
	89:13 96:1	50:3,7 57:5	147:8	
		58:18,19 59:7	transcription	
		59:8,9,11 60:4		

Michael Karram, M.D.

Page 168

111:1 134:9 136:2 turning 74:14 TVT 4:5,12,19 7:8 10:19 29:14,14,18,22 30:1,3,5 58:15 58:17,20 59:6 59:21 61:11 64:4,8,11,15 65:8,16,24 74:15 81:17 82:19 83:3 84:3 85:9,10 85:12,18,19,22 85:23,24 86:2 86:6,10,14,22 87:2,10 88:13 88:18,23 89:3 89:4,8 90:5,7 90:18 91:19,20 91:21,23 92:1 92:4,5,6,7,14 92:15,17 93:1 93:2,4,4,10,10 94:4,6 97:14 97:20,21 100:24 101:14 103:23 104:6,9 104:14,19,22 105:14,21,24 106:4,4 108:13 109:16 127:11 136:9 TVT-E 93:5,22 93:24 TVT-O 29:14 74:15 78:14 85:13 89:14,18 89:18 101:14 134:21 142:9 142:19 TVT-R 93:5 127:11 142:9 142:19 TVTs 129:21 twice 82:23	127:4 two 17:5,20 19:3 19:5 24:21,23 25:23 27:2 38:7 50:13 52:12 53:13,14 55:3,7,20 62:13 63:16 64:14 68:18 81:3 90:16 99:20 105:1 109:13 122:21 123:4 124:12 127:15,18 130:14,24 140:15 141:1 two-day 127:3 128:23 129:11 136:5,10 type 11:12 16:23 26:13 32:16 48:3 58:24 59:17 types 11:13 28:23 33:3 37:22 56:20,21 93:15 typical 37:11 123:4 typically 103:8 123:11 <hr/> U U.S 1:5 UC 135:17 Ulmsten 110:18 111:9 113:15 141:9,13,16 Ulmsten's 110:1 110:20 ultimately 70:5 Um-hmm 22:1,3 24:8 45:4 99:11 underneath 99:9 understand 8:13	41:20,23 42:6 42:12,17 53:6 71:6 82:12 83:24 88:9 126:10 137:15 137:20 139:13 140:1,7 understanding 8:23 17:16 111:18 119:12 understates 109:10 understood 67:1 80:12 111:22 124:22 140:10 undervalues 109:9 uniform 138:13 union 71:12,16 71:16 United 1:1 66:13 66:18 67:24 68:9,19 69:6 69:19 70:15 72:7 75:13 138:5 unreasonably 69:12 up-to-date 24:2 update 10:5 53:22 updated 10:4 22:22 40:24 urethra 59:15 60:13 64:23,24 urethropexy 101:12 urinary 4:20,24 8:18 29:6,7,8 29:10 30:6 59:5,22 62:11 83:8 108:14 110:15,23 114:19 115:6 115:17,20 116:8,14,18 117:2,7,11,16	117:22 118:2,4 118:8,10,15,17 120:10 142:10 143:12 urogyn 22:21,22 62:17 urogynecologist 120:8 143:5 urogynecology 8:8 62:12 119:17 urologist 13:8 Urology 34:8 42:22 43:2 use 22:7 36:18 51:9 55:24 57:2,5,9,18,20 57:24 58:2,7 58:10,12,21 59:10,10,21 60:11 61:6 65:20 84:16 85:9,10,12,24 86:12,14,23 87:16,19,20 88:6,18 89:9 89:22 92:5,14 92:19,23 93:24 94:5 102:6 105:2 107:7 114:20 115:7 115:13,17 116:9,19,21 117:3,7,11,16 117:22 118:3,8 118:15 119:2,9 usually 43:4 124:7,11 127:17,20 130:13 Uterine 35:15 uterus 139:8 utilize 71:19 utilized 11:12 12:5 95:3 <hr/> V	vagina 99:20 vaginal 4:19,23 48:4 56:1 108:13 110:13 110:22 118:4 118:10,17 vaginitis 38:5 vague 81:21 value 98:6 various 88:6 106:12 varying 53:14 vasa 46:2 vast 114:5 verbalize 41:24 verdict 47:10,10 47:13 48:20 version 26:2 62:1 85:13,15 90:7 versus 4:17 57:10 58:11 68:1 84:8 90:15 96:7,13 105:14 videos 10:11 violating 74:21 violation 66:15 68:15 69:13 VIRGINIA 1:1 viscus 99:18 100:5 Visibly 84:14 90:13 vitae 4:7,11 7:12 9:16,23 voiding 118:5,11 118:18 Volume 4:14 67:8 69:2 <hr/> W W 2:8 wage 33:20,21 waive 145:1 waived 3:13 145:2
--	---	---	---	---

Michael Karram, M.D.

Page 169

Walters 22:18 103:7	weight 59:1	words 115:16	yeah 83:20	86:5 110:16,19
Walters' 22:19	well-designed 95:24	120:6 127:10	88:22 98:2	110:20 144:20
Waltregny 78:16	well-known 113:21 114:1	143:6	109:3 132:9	10:02 1:14 3:2
want 59:12 88:9	well-recognized 65:8	work 14:14	134:14 135:10	100 33:23
89:22 109:22	Wendel 68:12	15:10 17:9,18	137:24	1020 2:15
113:8 136:9	69:9	18:7 24:11	year 19:3,6	108 4:19
wanted 11:8	Wendel's 72:9	26:21 28:15,18	24:14 45:24	11 5:3 128:5,7
105:15 129:20	went 31:1 43:7	28:23 33:5	50:10,15 59:18	110 4:22 106:14
135:20	47:9 48:21	36:8,21 38:9	59:19,20	12 5:5 20:8,20
wants 16:10	Wendel's 72:9	44:4,15,16,17	years 17:5,7,8	98:10 110:8
Ward 103:23	went 31:1 43:7	44:23 45:6	18:5,12 23:1	111:8,19 113:2
104:3,18	47:9 48:21	48:10 50:2,4	35:11 36:24	130:19,21
warm 123:20	93:21 107:24	50:17 55:7	40:20 50:16	131:22 142:1
Warren 68:12	124:7,9 131:6	58:5 121:17	55:3,7 56:19	12-month
69:8 72:20	weren't 89:14	132:1	70:13,19 86:3	141:18
wasn't 14:18	107:20 109:19	worked 9:3	142:1 144:20	125 33:23
25:1 46:9	127:16 129:19	25:10 30:12	144:20	128 5:3
103:4 126:6	137:10	40:3 114:4,8	<hr/> Z <hr/>	13 5:7 132:14,17
watch 16:5 43:5	WESLEY 2:9	working 27:4	Z-y-c-z-y-n-s...	132:18
43:11 126:4	WEST 1:1	35:3 71:22	77:19	130 5:5
135:14,16	Western 69:8	80:8	Zonies 2:4 6:4,5	132 5:7
watches 16:4	WHEREOF 147:12	worse 142:15	8:1,11 9:21	14 21:5
WAVE 4:10	within-named 147:5	worth 140:18	67:5,13 73:1,3	140 6:4
7:17	witness 3:7,12	wouldn't 37:1	88:2,4 113:14	1400 2:15
way 41:16 56:10	3:13 6:2 48:1	77:11 78:16	116:1 140:15	143 6:5
63:19,22 71:19	49:19 50:4,7	90:22 91:3	140:19 141:6	147 4:14 67:9
75:16 90:15	50:20,24 83:20	134:1	142:2,21 143:8	69:3
111:17,20	134:14 147:7	Wright 1:8	143:14,19	15 81:7,8 106:13
117:1 121:6,8	147:12	Wright's 27:24	Zyczynski 77:19	144:20
121:9,10 122:2	witnesses' 13:1	writing 20:15	<hr/> 0 <hr/>	16 81:7,8
122:7 138:12	woman 125:5	21:2 95:8	00789838	1700 2:5
139:1 142:13	140:6	137:5	128:11	18 106:13
147:9	woman's 143:7	written 20:11	03 37:23	18th 134:21
we'll 27:7 59:10	women 4:19	49:5 50:6	<hr/> 1 <hr/>	1900 2:5
67:5 103:2	37:21 108:13	62:14 73:6	1 4:4,10 7:6,17	1984 8:10 32:8,9
we're 18:1 26:8	109:17 110:8	116:6	9:5,15 10:9	1988 32:20
50:3,7,14	111:10 138:22	wrong 124:19	14:10,22 20:8	1998 30:7 32:10
53:21 93:14	143:12	134:16	21:21 27:14	32:10
102:19 114:13	Women's 32:5	wrote 71:24	52:8,12,13	1999 34:7,11,21
145:1	34:7 42:21	73:9 94:15	68:15,23 69:13	35:5 36:11
we've 55:2 66:6	43:2	Wyoming 48:2	1,000 18:20	43:1 56:15
67:14 138:15	Woods 133:24	48:11 49:18	1,500 18:21	59:21 110:2,20
week 89:15	word 12:13	50:2	1,750 135:1	1st 147:13
134:3	82:22 108:23	<hr/> X <hr/>	10 4:12,22 14:22	<hr/> 2 <hr/>
weekend 18:16	115:4 141:13	<hr/> Y <hr/>		2 4:5,14 5:3 7:10
				23:13 25:5

Michael Karram, M.D.

Page 170

26:22 29:1	134:21	2:6	67 4:14
55:12 67:9	2010 35:11	31st 57:7	<hr/>
128:15 129:8	43:23 47:3	3300 1:17	7
136:3	49:14	334-269-2343	7 4:4,5,7,8,14
2,000 56:13	2010ish 40:21	2:11	6:4 67:6,11,14
101:24 143:6	2011 17:24 18:3	349 111:2,4	123:24
2,500 18:15	35:11 43:21,23	141:17	7:00 124:3,4
2.7 99:4	82:7 139:22	350 102:14	129:8
2:12-cv-00368	2012 18:3,6,23	36 110:9 111:9	7:30 131:9
1:9	43:21 48:9	113:2 141:23	70 4:14 56:23
2:12-cv-00481	49:12,18	142:1	67:8 69:3
1:10	2013 55:16	36104 2:10	76 73:11,17,18
2:12-cv-00746	2014 24:16 81:6	39157 2:16	73:21
1:9	82:15	<hr/>	77 106:12
2:12-cv-00880	2015 24:15	4	<hr/>
1:8	55:16,23 70:21	4 4:8 7:18 75:19	8
2:12-cv-00938	82:10	111:4	8 4:16 14:10
1:10	2016 1:13 3:1	4/2 134:6,7,7	20:8,19,20
2:12-cv-01090	18:1 34:13	4/2/2008 133:14	96:9,11 98:21
1:8	145:5 147:13	4/3 134:5	147:17
2:12-MD-02327	2017 147:17	4/7 134:5	800,000 47:14
1:4	218 2:10	42 32:15	80202 2:5
2:36 145:4	2327 1:4	44 97:10	81 101:16
20 56:24 81:6	24 110:9 111:9	44,000 73:14	82% 109:7
144:20 146:15	111:19 113:2	44,387 73:15	84 101:11
2000 60:3 63:11	24/36-month	44376-44387	87 73:16
2000s 60:3	141:19	4:15 67:10	877.370.3377
2002 37:5 39:18	24th 68:5,9 69:6	44377 69:3	1:23
72:8 103:23	25 56:24	44387 73:11	88 101:13,15
104:2,5	28 109:6	<hr/>	<hr/>
2003 36:12	28(D) 147:11	5	9
38:11,24 72:8	28,000 25:20	5 4:11 9:24 10:3	9 4:11,19 108:16
72:22	26:1,21	24:3 35:14	108:18 109:5
2004 17:4,9,23	29 1:13 3:1	123:24	109:11
18:5,23 37:5	145:4	50 25:14	9% 109:7,8
37:23 38:24	2nd 67:18	500 28:22	9,000 25:22 26:5
39:18 40:11	<hr/>	55.8 97:5	26:11
73:5 79:8,24	3	<hr/>	9:00 124:8
2005 4:15 17:4	3 4:7 7:13 24:1	6	94 108:8
42:20 43:13	32:2 109:7,8	6 4:12 9:9 10:21	96 4:16
67:9,18 68:5,9	109:11	10:24	
69:6	3,000 18:16	60 101:10	
2006 32:20	3/2/2016 75:23	601-948-5711	
44:11	3:15 131:7,10,11	2:16	
2008 133:1	300 102:14	62.2 97:5	
139:22	301 1:17	65 25:14 27:12	
2009 86:5	303-893-6100	28:14,18 56:23	